King Pharmaceuticals

Meridian Medical Technologies.
a subsidiary of
King Pharmaceuticals,® Inc.

6350 Stevens Forest Road, Suite 301
Columbia, MD 21046

Sean Cowherd
Account Representative

May 21, 2007

Roberta Wagner
Health and Human Resources
505 Capital Street, Suite 200
Charleston, WV 25301

Re: RFQ#BPH70353

Dear Roberta,

As the sole manufacturer of chemical nerve agent antidote auto-injectors, we believe there was a little bit of confusion in determining the specifications for RFQ# BPH70353.

Our DuoDote™ auto injector provides 2.1 mg of Atropine and 600 mg Pralidoxime Chloride in separate chambers as sterile, pyrogen-free solutions for intramuscular injections. When activated, the auto-injector administers atropine and pralidoxime chloride using a single 0.8 inch, 23 gauge needle. This product contains up to a 3 year shelf life.

Our Mark 1™ kit contains 2.0 mg of Atropine and 600 mg of Pralidoxime Chloride, but is in two separate injections. Each needle is 22 gauge, and the product contains up to a 5 year shelf life.

Meridian also manufacturers a compliment of auto-injector training simulators for instruction in the proper use of the auto-injector. These training simulators are similar in appearance and function to the auto-injector drug delivery systems they mimic.

I have included bid pricing on both auto-injectors, as well as a sample trainer. If you need any further information, please feel free to call me at 443-259-7878.

Best regards,

Sean Cowherd
Account Representative
Commercial Pharmaceuticals

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
BPH70353	1

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
Meridian Medical Technologies
Attention: Ireatha Woods
6350 Stevens Forest Road, Suite 301
Columbia, MD 21046

SHIP TO
HEALTH AND HUMAN RESOURCES
BPH - THREAT PREPAREDNESS
505 CAPITOL STREET, SUITE 200
CHARLESTON, WV
25301 304-558-1218

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
05/01/2007				

BID OPENING DATE: 05/31/2007 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
0001	6,000	EA		475-78	$29.14	$174,840.00

Mark I

CHEMICAL NERVE AGENT ANTIDOTE AUTO-INJECTORS

PER THE ATTACHED SPECIFICATIONS.

0002	250	EA		475-78	$25.84	$ 6,460.00

Mark I

AUTO-INJECTOR TRAINING SIMULATORS

PER THE ATTACHED SPECIFICATIONS.

TO BE DELIVERED WITHIN 30 CALENDAR DAYS AFTER RECEIPT OF ORDER (ARO).

CANCELLATION: THE DIRECTOR OF PURCHASING RESERVES THE RIGHT TO CANCEL THIS CONTRACT IMMEDIATELY UPON WRITTEN NOTICE TO THE VENDOR IF THE COMMODITIES AND/OR SERVICES SUPPLIED ARE OF AN INFERIOR QUALITY OR DO NOT CONFORM TO THE SPECIFICATIONS OF THE BID AND CONTRACT HEREIN.

BANKRUPTCY: IN THE EVENT THE VENDOR/CONTRACTOR FILES FOR BANKRUPTCY PROTECTION, THIS CONTRACT IS AUTOMATICALLY NULL AND VOID, AND IS TERMINATED WITHOUT FURTHER ORDER.

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE _____ TELEPHONE 443 259 7878 DATE 5/11/07

TITLE Account Rep FEIN 52-0898764 ADDRESS CHANGES TO BE NOTED ABOVE

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
BPH70353	2

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

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INQUIRIES
WRITTEN QUESTIONS SHALL BE ACCEPTED THROUGH CLOSE OF BUSINESS ON MAY 16, 2007. QUESTIONS MAY BE SENT VIA USPS, FAX, COURIER OR E-MAIL. IN ORDER TO ASSURE NO VENDOR RECEIVES AN UNFAIR ADVANTAGE, NO SUBSTANTIVE QUESTIONS WILL BE ANSWERED ORALLY. IF POSSIBLE, E-MAIL QUESTIONS ARE PREFERRED. ADDRESS INQUIRIES TO:

ROBERTA WAGNER
DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
2019 WASHINGTON STREET, EAST
CHARLESTON, WV 25311

FAX: 304-558-4115
E-MAIL: RWAGNER@WVADMIN.GOV

VENDOR PREFERENCE CERTIFICATE

CERTIFICATION AND APPLICATION* IS HEREBY MADE FOR PREFERENCE IN ACCORDANCE WITH WEST VIRGINIA CODE, 5A-3-37 (DOES NOT APPLY TO CONSTRUCTION CONTRACTS).

A. APPLICATION IS MADE FOR 2.5% PREFERENCE FOR THE REASON CHECKED:

( ) BIDDER IS AN INDIVIDUAL RESIDENT VENDOR AND HAS RESIDED CONTINUOUSLY IN WEST VIRGINIA FOR FOUR (4) YEARS IMMEDIATELY PRECEDING THE DATE OF THIS CERTIFICATION; OR

( ) BIDDER IS A PARTNERSHIP, ASSOCIATION OR CORPORATION RESIDENT VENDOR AND HAS MAINTAINED ITS HEAD-

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
	443 259 7878	5/11/07

TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE
Account Representative	52-0898764	

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

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304-558-0067

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QUARTERS OR PRINCIPAL PLACE OF BUSINESS CONTINUOUSLY IN WEST VIRGINIA FOR FOUR (4) YEARS IMMEDIATELY PRECEDING THE DATE OF THIS CERTIFICATION; OR 80% OF THE OWNERSHIP INTEREST OF BIDDER IS HELD BY ANOTHER INDIVIDUAL, PARTNERSHIP, ASSOCIATION OR CORPORATION RESIDENT VENDOR WHO HAS MAINTAINED ITS HEADQUARTERS OR PRINCIPAL PLACE OF BUSINESS CONTINUOUSLY IN WEST VIRGINIA FOR FOUR (4) YEARS IMMEDIATELY PRECEDING THE DATE OF THIS CERTIFICATION; OR

( ) BIDDER IS A CORPORATION NONRESIDENT VENDOR WHICH HAS AN AFFILIATE OR SUBSIDIARY WHICH EMPLOYS A MINIMUM OF ONE HUNDRED STATE RESIDENTS AND WHICH HAS MAINTAINED ITS HEADQUARTERS OR PRINCIPAL PLACE OF BUSINESS WITHIN WEST VIRGINIA CONTINUOUSLY FOR THE FOUR (4) YEARS IMMEDIATELY PRECEDING THE DATE OF THIS CERTIFICATION.

B. APPLICATION IS MADE FOR 2.5% PREFERENCE FOR THE REASON CHECKED:

( ) BIDDER IS A RESIDENT VENDOR WHO CERTIFIES THAT, DURING THE LIFE OF THE CONTRACT, ON AVERAGE AT LEAST 75% OF THE EMPLOYEES WORKING ON THE PROJECT BEING BID ARE RESIDENTS OF WEST VIRGINIA WHO HAVE RESIDED IN THE STATE CONTINUOUSLY FOR THE TWO YEARS IMMEDIATELY PRECEDING SUBMISSION OF THIS BID;
OR
( ) BIDDER IS A NONRESIDENT VENDOR EMPLOYING A MINIMUM OF ONE HUNDRED STATE RESIDENTS OR IS A NONRESIDENT VENDOR WITH AN AFFILIATE OR SUBSIDIARY WHICH MAINTAINS ITS HEADQUARTERS OR PRINCIPAL PLACE OF BUSINESS WITHIN WEST VIRGINIA EMPLOYING A MINIMUM OF ONE HUNDRED STATE RESIDENTS WHO CERTIFIES THAT, DURING THE LIFE OF THE CONTRACT, ON AVERAGE AT LEAST 75% OF THE EMPLOYEES OR BIDDERS' AFFILIATE'S OR

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 443 259 7878 DATE 5/11/07

Account Representative FEIN 52-0898764 ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
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Charleston, WV 25305-0130

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RFQ NUMBER	PAGE
BPH70353	4

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

SHIP TO
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CHARLESTON, WV
25301 304-558-1218

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05/01/2007				

BID OPENING DATE: 05/31/2007 BID OPENING TIME 01:30PM

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SUBSIDIARY'S EMPLOYEES ARE RESIDENTS OF WEST VIRGINIA WHO HAVE RESIDED IN THE STATE CONTINUOUSLY FOR THE TWO YEARS IMMEDIATELY PRECEDING SUBMISSION OF THIS BID.

BIDDER UNDERSTANDS IF THE SECRETARY OF TAX & REVENUE DETERMINES THAT A BIDDER RECEIVING PREFERENCE HAS FAILED TO CONTINUE TO MEET THE REQUIREMENTS FOR SUCH PREFERENCE, THE SECRETARY MAY ORDER THE DIRECTOR OF PURCHASING TO: (A) RESCIND THE CONTRACT OR PURCHASE ORDER ISSUED; OR (B) ASSESS A PENALTY AGAINST SUCH BIDDER IN AN AMOUNT NOT TO EXCEED 5% OF THE BID AMOUNT AND THAT SUCH PENALTY WILL BE PAID TO THE CONTRACTING AGENCY OR DEDUCTED FROM ANY UNPAID BALANCE ON THE CONTRACT OR PURCHASE ORDER.

BY SUBMISSION OF THIS CERTIFICATE, BIDDER AGREES TO DISCLOSE ANY REASONABLY REQUESTED INFORMATION TO THE PURCHASING DIVISION AND AUTHORIZES THE DEPARTMENT OF TAX AND REVENUE TO DISCLOSE TO THE DIRECTOR OF PURCHASING APPROPRIATE INFORMATION VERIFYING THAT BIDDER HAS PAID THE REQUIRED BUSINESS TAXES, PROVIDED THAT SUCH INFORMATION DOES NOT CONTAIN THE AMOUNTS OF TAXES PAID NOR ANY OTHER INFORMATION DEEMED BY THE TAX COMMISSIONER TO BE CONFIDENTIAL.

UNDER PENALTY OF LAW FOR FALSE SWEARING (WEST VIRGINIA CODE 61-5-3), BIDDER HEREBY CERTIFIES THAT THIS CERTIFICATE IS TRUE AND ACCURATE IN ALL RESPECTS; AND THAT IF A CONTRACT IS ISSUED TO BIDDER AND IF ANYTHING CONTAINED WITHIN THIS CERTIFICATE CHANGES DURING THE TERM OF THE CONTRACT, BIDDER WILL NOTIFY THE PURCHASING DIVISION IN WRITING IMMEDIATELY.

BIDDER: Meridian Medical Technologies

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE _____ TELEPHONE 443 259 7878 DATE 5/11/07

TITLE Account Representative FEIN 52-0898164 ADDRESS CHANGES TO BE NOTED ABOVE

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
BPH70353	5

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

SHIP TO
HEALTH AND HUMAN RESOURCES
BPH - THREAT PREPAREDNESS

505 CAPITOL STREET, SUITE 200
CHARLESTON, WV
25301 304-558-1218

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
05/01/2007				

BID OPENING DATE: 05/31/2007 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT

DATE: 5/11/07

SIGNED: [signature]

TITLE: Account Representative

* CHECK ANY COMBINATION OF PREFERENCE CONSIDERATION(S) IN EITHER "A" OR "B", OR BOTH "A" AND "B" WHICH YOU ARE ENTITLED TO RECEIVE. YOU MAY REQUEST UP TO THE MAXIMU 5% PREFERENCE FOR BOTH "A" AND "B".
(REV. 12/00)

NOTICE

A SIGNED BID MUST BE SUBMITTED TO:

DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
BUILDING 15
2019 WASHINGTON STREET, EAST
CHARLESTON, WV 25305-0130

PLEASE NOTE A CONVENIENCE COPY WOULD BE APPRECIATED.

THE BID SHOULD CONTAIN THIS INFORMATION ON THE FACE OF THE ENVELOPE OR THE BID MAY NOT BE CONSIDERED:

SEALED BID

BUYER:----------ROBERTA WAGNER/FILE 22----------

RFQ. NO.:----------BPH70353----------

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 443 259 7870 DATE 5/11/07

TITLE Account Rep FEIN 52-0898764 ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
BPH70353	6

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

SHIP TO
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505 CAPITOL STREET, SUITE 200
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05/01/2007				

BID OPENING DATE: 05/31/2007 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT

BID OPENING DATE:-------MAY 31, 2007----------

BID OPENING TIME:-------1:30 PM----------

PLEASE PROVIDE A FAX NUMBER IN CASE IT IS NECESSARY TO CONTACT YOU REGARDING YOUR BID:

443 259 7801

CONTACT PERSON (PLEASE PRINT CLEARLY):

Sean Cowherd

* Per addendum 1, there will be a shipping/handling charge of $389.00 — $389.00

****** THIS IS THE END OF RFQ BPH70353 ****** TOTAL: $181,689.00

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE

TELEPHONE 443 259 7878

DATE 5/11/07

TITLE Account Representative

FEIN 52-0898764

ADDRESS CHANGES TO BE NOTED ABOVE

"SPECIFICATIONS"

RFQ: BPH70353

The West Virginia Office of Emergency Medical Services and the West Virginia Division of Threat Preparedness, divisions of the West Virginia Department of Health and Human Resources, Bureau for Public Health, is soliciting bids for the purchase of:

1. 6000 ea. **Must provide *FDA-approved chemical nerve agent antidote auto-injectors.***

   The auto-injector shall provide Atropine Injection and Pralidoxime Chloride Injection in separate chambers as sterile, pyrogen-free solutions for intramuscular injection - specially designed for automatic self- or buddy-administration. When activated, the auto-injector shall sequentially administer atropine and pralidoxime chloride using a single 0.8 inch, 18-gauge needle to inject the contents of the auto-injector into the muscles of an outer thigh or into the buttocks. Upon activation, the auto-injector shall dispense 2.1 mg atropine (in 0.7 mL of a sterile, pyrogen-free solution containing 12.47 mg glycerin and not more than 2.8 mg phenol, citrate buffer, and water for injection with a pH range of 4.0 – 5.0) and 600 mg of pralidoxime chloride (in 2 mL of a sterile, pyrogen-free solution containing 40 mg benzyl alcohol, 22.5 mg glycine, and water for injection with a pH range of 2.0 – 3.0.)

   The auto-injector must be designed to be non-refillable, and in such a way that the protruding needle cannot be retracted. The auto-injector must have a minimum of a four-year (48 months) shelf life with at least 42 months remaining in the shelf-life upon receipt of the auto-injectors by the divisions.

   Bid price must include all costs related to the purchase and delivery of the auto-injectors to the F.O.B. Destination. Delivery at the final destination shall be within thirty (30) calendar days after receipt of order (ARO). Damage to items in transit will be the sole responsibility of the vendor. The vendor will be obligated to file any claims against carrier(s) for any damage incurred while in transit from point of origin to the ultimate destination.

2. 250 ea. Must provide auto-injector training simulators. These simulator must be similar in appearance and function to the auto-injector drug delivery systems they mimic. Unlike their prescription counterparts, they do not contain a needle or any medication and can be reset after activation for repeated educational demonstration or for training excercises.

COST EVALUATION SHEET FOR RFQ BPH70353

Item	Description	Quantity	Unit Cost	Total Cost
Mark I kits	1 Auto-Injector (6000 lot size) as specified in document.	6000	$29.14	$174,840.00
	2 Trainers as specified in document.	250	$25.84	$ 6,460.00
Mark I	3. Shipping/Handling (per addendum 1)	1	$389.00	$ 389.00
			GRAND TOTAL:	$181,689.00

800

RFQ No. BPH70353

STATE OF WEST VIRGINIA
Purchasing Division

009

PURCHASING AFFIDAVIT

West Virginia Code §5A-3-10a states: No contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and the debt owned is an amount greater than one thousand dollars in the aggregate

DEFINITIONS:
"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Debtor" means any individual, corporation, partnership, association, limited liability company or any other form or business association owing a debt to the state or any of its political subdivisions. "Political subdivision" means any county commission; municipality; county board of education; any instrumentality established by a county or municipality; any separate corporation or instrumentality established by one or more counties or municipalities, as permitted by law; or any public body charged by law with the performance of a government function or whose jurisdiction is coextensive with one or more counties or municipalities. "Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

EXCEPTION: The prohibition of this section does not apply where a vendor has contested any tax administered pursuant to chapter eleven of this code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

LICENSING: Vendors must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, West Virginia Insurance Commission, or any other state agencies or political subdivision. Furthermore, the vendor must provide all necessary releases to obtain information to enable the Director or spending unit to verify that the vendor is licensed and in good standing with the above entities.

CONFIDENTIALITY: The vendor agrees that he or she will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the agency's policies, procedures and rules. Vendors should visit **www.state.wv.us/admin/purchase/privacy** for the Notice of Agency Confidentiality Policies.

Under penalty of law for false swearing (West Virginia Code, §61-5-3), it is hereby certified that the vendor acknowledges the information in this said affidavit and are in compliance with the requirements as stated.

Vendor's Name: Meridian Medical Technologies, Inc.

Authorized Signature: _____ Date: 5/11/07

MERIDIAN
MEDICAL TECHNOLOGIES™

A Subsidiary of King Pharmaceuticals, Inc.

May 21st, 2007

Re: Sole Manufacturer of FDA-approved Chemical Nerve Agent Antidote Auto-Injectors

Dear Deron:

As we recently discussed, MERIDIAN MEDICAL TECHNOLOGIES™, INC. is the sole manufacturer of FDA-approved chemical nerve agent antidote auto-injectors as well as other auto-injector drug delivery systems. Our products include:

- AtroPen® 2 mg Auto-Injector (atropine injection)
- AtroPen® 1 mg Auto-Injector (atropine injection)
- AtroPen® 0.5 mg Auto-Injector (atropine injection)
- AtroPen® 0.25 mg Auto-Injector (atropine injection)
- Diazepam 10 mg Auto-Injector (diazepam injection) C-IV
- DuoDote™ Auto-Injector (atropine and pralidoxime chloride injection)
- Mark I™, Nerve Agent Antidote Kit (NAAK), comprised of AtroPen® 2 mg Auto-Injector (atropine injection) and Pralidoxime Chloride 600 mg Auto-Injector (pralidoxime chloride injection)
- Morphine 10 mg Auto-Injector (morphine injection) C-II
- Pralidoxime Chloride 600 mg Auto-Injector (pralidoxime chloride injection)

MERIDIAN also manufacturers a compliment of auto-injector training simulators for instruction in the proper use of the auto-injector. These training simulators are similar in appearance and function to the auto-injector drug delivery systems they mimic.

Meridian Medical Technologies™, Inc. has an agreement with a distributor for our EMS market. The distributor handles our product inquiries at the local level only. Meridian Medical Technologies™, Inc. serves the county, state and federal markets for all product inquiries.

If you need any further information, please feel free to call me at 443-259-7878.

Best regards,

Sean Cowherd
Account Representative, Commercial Pharmaceuticals

SC/

King Pharmaceuticals

Columbia, MD 21046 USA
443.259.7800 fax 443.259.7801
Email: info@meridianmt.com
Internet: www.meridianmeds.com

State of West Virginia
Department of Administration
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BID OPENING DATE: 05/31/2007 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
0001 Duodote	6,000	EA		475-78	$33.44	$200,640.00
	CHEMICAL NERVE AGENT ANTIDOTE AUTO-INJECTORS					
	PER THE ATTACHED SPECIFICATIONS.					
0002 Duodote	250	EA		475-78	$12.51	$3,127.50
	AUTO-INJECTOR TRAINING SIMULATORS					
	PER THE ATTACHED SPECIFICATIONS.					
	TO BE DELIVERED WITHIN 30 CALENDAR DAYS AFTER RECEIPT OF ORDER (ARO).					
	CANCELLATION: THE DIRECTOR OF PURCHASING RESERVES THE RIGHT TO CANCEL THIS CONTRACT IMMEDIATELY UPON WRITTEN NOTICE TO THE VENDOR IF THE COMMODITIES AND/OR SERVICES SUPPLIED ARE OF AN INFERIOR QUALITY OR DO NOT CONFORM TO THE SPECIFICATIONS OF THE BID AND CONTRACT HEREIN.					
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SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 443 259 7878 DATE 5/11/07

TITLE Account Representative FEIN 52-0898764 ADDRESS CHANGES TO BE NOTED ABOVE

FORM INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
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WRITTEN QUESTIONS SHALL BE ACCEPTED THROUGH CLOSE OF BUSINESS ON MAY 16, 2007. QUESTIONS MAY BE SENT VIA USPS, FAX, COURIER OR E-MAIL. IN ORDER TO ASSURE NO VENDOR RECEIVES AN UNFAIR ADVANTAGE, NO SUBSTANTIVE QUESTIONS WILL BE ANSWERED ORALLY. IF POSSIBLE, E-MAIL QUESTIONS ARE PREFERRED. ADDRESS INQUIRIES TO:

ROBERTA WAGNER
DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
2019 WASHINGTON STREET, EAST
CHARLESTON, WV 25311

FAX: 304-558-4115
E-MAIL: RWAGNER@WVADMIN.GOV

VENDOR PREFERENCE CERTIFICATE

CERTIFICATION AND APPLICATION* IS HEREBY MADE FOR PREFERENCE IN ACCORDANCE WITH WEST VIRGINIA CODE, 5A-3-37 (DOES NOT APPLY TO CONSTRUCTION CONTRACTS).

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( ) BIDDER IS A PARTNERSHIP, ASSOCIATION OR CORPORATION RESIDENT VENDOR AND HAS MAINTAINED ITS HEAD-

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ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

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HEALTH AND HUMAN RESOURCES
BPH - THREAT PREPAREDNESS

505 CAPITOL STREET, SUITE 200
CHARLESTON, WV
25301 304-558-1218

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
05/01/2007				

BID OPENING DATE: 05/31/2007 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT. NO.	ITEM NUMBER	UNIT PRICE	AMOUNT

QUARTERS OR PRINCIPAL PLACE OF BUSINESS CONTINUOUSLY IN WEST VIRGINIA FOR FOUR (4) YEARS IMMEDIATELY PRECEDING THE DATE OF THIS CERTIFICATION; OR 80% OF THE OWNERSHIP INTEREST OF BIDDER IS HELD BY ANOTHER INDIVIDUAL, PARTNERSHIP, ASSOCIATION OR CORPORATION RESIDENT VENDOR WHO HAS MAINTAINED ITS HEADQUARTERS OR PRINCIPAL PLACE OF BUSINESS CONTINUOUSLY IN WEST VIRGINIA FOR FOUR (4) YEARS IMMEDIATELY PRECEDING THE DATE OF THIS CERTIFICATION; OR

( ) BIDDER IS A CORPORATION NONRESIDENT VENDOR WHICH HAS AN AFFILIATE OR SUBSIDIARY WHICH EMPLOYS A MINIMUM OF ONE HUNDRED STATE RESIDENTS AND WHICH HAS MAINTAINED ITS HEAQUARTERS OR PRINCIPAL PLACE OF BUSINESS WITHIN WEST VIRGINIA CONTINUOUSLY FOR THE FOUR (4) YEARS IMMEDIATELY PRECEDING THE DATE OF THIS CERTIFICATION.

B. APPLICATION IS MADE FOR 2.5% PREFERENCE FOR THE REASON CHECKED:

( ) BIDDER IS A RESIDENT VENDOR WHO CERTIFIES THAT, DURING THE LIFE OF THE CONTRACT, ON AVERAGE AT LEAST 75% OF THE EMPLOYEES WORKING ON THE PROJECT BEING BID ARE RESIDENTS OF WEST VIRGINIA WHO HAVE RESIDED IN THE STATE CONTINUOUSLY FOR THE TWO YEARS IMMEDIATELY PRECEDING SUBMISSION OF THIS BID;
OR
( ) BIDDER IS A NONRESIDENT VENDOR EMPLOYING A MINIMUM OF ONE HUNDRED STATE RESIDENTS OR IS A NONRESIDENT VENDOR WITH AN AFFILIATE OR SUBSIDIARY WHICH MAINTAINS ITS HEADQUARTERS OR PRINCIPAL PLACE OF BUSINESS WITHIN WEST VIRGINIA EMPLOYING A MINIMUM OF ONE HUNDRED STATE RESIDENTS WHO CERTIFIES THAT, DURING THE LIFE OF THE CONTRACT, ON AVERAGE AT LEAST 75% OF THE EMPLOYEES OR BIDDERS' AFFILIATE'S OR

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

NATURE [signature] TELEPHONE 443 259 7878 DATE 5/11/07

LE Account Representative FEIN 52-0898764 ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
BPH70353	4

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

SHIP TO
HEALTH AND HUMAN RESOURCES
BPH - THREAT PREPAREDNESS

505 CAPITOL STREET, SUITE 200
CHARLESTON, WV
25301 304-558-1218

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05/01/2007				

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SUBSIDIARY'S EMPLOYEES ARE RESIDENTS OF WEST VIRGINIA WHO HAVE RESIDED IN THE STATE CONTINUOUSLY FOR THE TWO YEARS IMMEDIATELY PRECEDING SUBMISSION OF THIS BID.

BIDDER UNDERSTANDS IF THE SECRETARY OF TAX & REVENUE DETERMINES THAT A BIDDER RECEIVING PREFERENCE HAS FAILED TO CONTINUE TO MEET THE REQUIREMENTS FOR SUCH PREFERENCE, THE SECRETARY MAY ORDER THE DIRECTOR OF PURCHASING TO: (A) RESCIND THE CONTRACT OR PURCHASE ORDER ISSUED; OR (B) ASSESS A PENALTY AGAINST SUCH BIDDER IN AN AMOUNT NOT TO EXCEED 5% OF THE BID AMOUNT AND THAT SUCH PENALTY WILL BE PAID TO THE CONTRACTING AGENCY OR DEDUCTED FROM ANY UNPAID BALANCE ON THE CONTRACT OR PURCHASE ORDER.

BY SUBMISSION OF THIS CERTIFICATE, BIDDER AGREES TO DISCLOSE ANY REASONABLY REQUESTED INFORMATION TO THE PURCHASING DIVISION AND AUTHORIZES THE DEPARTMENT OF TAX AND REVENUE TO DISCLOSE TO THE DIRECTOR OF PURCHASING APPROPRIATE INFORMATION VERIFYING THAT BIDDER HAS PAID THE REQUIRED BUSINESS TAXES, PROVIDED THAT SUCH INFORMATION DOES NOT CONTAIN THE AMOUNTS OF TAXES PAID NOR ANY OTHER INFORMATION DEEMED BY THE TAX COMMISSIONER TO BE CONFIDENTIAL.

UNDER PENALTY OF LAW FOR FALSE SWEARING (WEST VIRGINIA CODE 61-5-3), BIDDER HEREBY CERTIFIES THAT THIS CERTIFICATE IS TRUE AND ACCURATE IN ALL RESPECTS; AND THAT IF A CONTRACT IS ISSUED TO BIDDER AND IF ANYTHING CONTAINED WITHIN THIS CERTIFICATE CHANGES DURING THE TERM OF THE CONTRACT, BIDDER WILL NOTIFY THE PURCHASING DIVISION IN WRITING IMMEDIATELY.

BIDDER: ---------- Meridian Medical Technologies

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE	TELEPHONE	DATE
	443-259-7878	5/11/07

TITLE	FEIN	ADDRESS CHANGES TO BE NOTED ABOVE
Account Representative	52-0898764	

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
BPH70353	5

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

SHIP TO
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505 CAPITOL STREET, SUITE 200
CHARLESTON, WV
25301 304-558-1218

DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
05/01/2007				

BID OPENING DATE: 05/31/2007 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT

DATE: 5/11/07

SIGNED: [signature]

TITLE: Account Representative

* CHECK ANY COMBINATION OF PREFERENCE CONSIDERATION(S) IN EITHER "A" OR "B", OR BOTH "A" AND "B" WHICH YOU ARE ENTITLED TO RECEIVE. YOU MAY REQUEST UP TO THE MAXIMU 5% PREFERENCE FOR BOTH "A" AND "B".
(REV. 12/00)

NOTICE

A SIGNED BID MUST BE SUBMITTED TO:

DEPARTMENT OF ADMINISTRATION
PURCHASING DIVISION
BUILDING 15
2019 WASHINGTON STREET, EAST
CHARLESTON, WV 25305-0130

PLEASE NOTE A CONVENIENCE COPY WOULD BE APPRECIATED.

THE BID SHOULD CONTAIN THIS INFORMATION ON THE FACE OF THE ENVELOPE OR THE BID MAY NOT BE CONSIDERED:

SEALED BID

BUYER:----------ROBERTA WAGNER/FILE 22----------

RFQ. NO.:----------BPH70353----------

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

NATURE [signature] TELEPHONE 443 259 7878 DATE 5/11/07

LE Account Representative FEIN 52-0898764 ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

State of West Virginia
Department of Administration
Purchasing Division
2019 Washington Street East
Post Office Box 50130
Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER	PAGE
BPH70353	6

ADDRESS CORRESPONDENCE TO ATTENTION OF:
ROBERTA WAGNER
304-558-0067

VENDOR
RFQ COPY
TYPE NAME/ADDRESS HERE

SHIP TO
HEALTH AND HUMAN RESOURCES
BPH - THREAT PREPAREDNESS

505 CAPITOL STREET, SUITE 200
CHARLESTON, WV
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DATE PRINTED	TERMS OF SALE	SHIP VIA	F.O.B.	FREIGHT TERMS
05/01/2007				

BID OPENING DATE: 05/31/2007 BID OPENING TIME 01:30PM

LINE	QUANTITY	UOP	CAT NO	ITEM NUMBER	UNIT PRICE	AMOUNT
				BID OPENING DATE:------MAY 31, 2007----------		
				BID OPENING TIME:-------1:30 PM----------		
				PLEASE PROVIDE A FAX NUMBER IN CASE IT IS NECESSARY TO CONTACT YOU REGARDING YOUR BID:		
				443 259 7801		
				CONTACT PERSON (PLEASE PRINT CLEARLY):		
				Sean Cowherd		
				* per addendum 1, there will be a shipping/handling charge of $389.00		$ 389.00
				****** THIS IS THE END OF RFQ BPH70353 ****** TOTAL:		$ 204,156.50

SEE REVERSE SIDE FOR TERMS AND CONDITIONS

SIGNATURE [signature] TELEPHONE 443 259 7878 DATE 5/11/07

TITLE Account Representative FEIN 52-0898764 ADDRESS CHANGES TO BE NOTED ABOVE

WHEN RESPONDING TO RFQ, INSERT NAME AND ADDRESS IN SPACE ABOVE LABELED 'VENDOR'

"SPECIFICATIONS"

RFQ: BPH70353

The West Virginia Office of Emergency Medical Services and the West Virginia Division of Threat Preparedness, divisions of the West Virginia Department of Health and Human Resources, Bureau for Public Health, is soliciting bids for the purchase of:

1. 6000 ea. **Must provide *FDA-approved chemical nerve agent antidote auto-injectors.***

   The auto-injector shall provide Atropine Injection and Pralidoxime Chloride Injection in separate chambers as sterile, pyrogen-free solutions for intramuscular injection - specially designed for automatic self- or buddy-administration. When activated, the auto-injector shall sequentially administer atropine and pralidoxime chloride using a single 0.8 inch, 18-gauge needle to inject the contents of the auto-injector into the muscles of an outer thigh or into the buttocks. Upon activation, the auto-injector shall dispense 2.1 mg atropine (in 0.7 mL of a sterile, pyrogen-free solution containing 12.47 mg glycerin and not more than 2.8 mg phenol, citrate buffer, and water for injection with a pH range of 4.0 – 5.0) and 600 mg of pralidoxime chloride (in 2 mL of a sterile, pyrogen-free solution containing 40 mg benzyl alcohol, 22.5 mg glycine, and water for injection with a pH range of 2.0 – 3.0.)

   The auto-injector must be designed to be non-refillable, and in such a way that the protruding needle cannot be retracted. The auto-injector must have a minimum of a four-year (48 months) shelf life with at least 42 months remaining in the shelf-life upon receipt of the auto-injectors by the divisions.

   Bid price must include all costs related to the purchase and delivery of the auto-injectors to the F.O.B. Destination. Delivery at the final destination shall be within thirty (30) calendar days after receipt of order (ARO). Damage to items in transit will be the sole responsibility of the vendor. The vendor will be obligated to file any claims against carrier(s) for any damage incurred while in transit from point of origin to the ultimate destination.

2. 250 ea. Must provide auto-injector training simulators. These simulator must be similar in appearance and function to the auto-injector drug delivery systems they mimic. Unlike their prescription counterparts, they do not contain a needle or any medication and can be reset after activation for repeated educational demonstration or for training excercises.

COST EVALUATION SHEET FOR RFQ BPH70353

Item	Description	Quantity	Unit Cost	Total Cost
Duodote 1	Auto-Injector (6000 lot size) as specified in document.	6000	$33.44	$200,640.00
Duodote 2	Trainers as specified in document.	250	$ 12.51	$ 3,127.50
3.	Shipping/Handling (per addendum 1)	1	389.00	$ 389.00
			GRAND TOTAL:	$204,156.50

800

RFQ No. BPH70353

STATE OF WEST VIRGINIA
Purchasing Division

009

PURCHASING AFFIDAVIT

West Virginia Code §5A-3-10a states: No contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and the debt owned is an amount greater than one thousand dollars in the aggregate

DEFINITIONS:
"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Debtor" means any individual, corporation, partnership, association, limited liability company or any other form or business association owing a debt to the state or any of its political subdivisions. "Political subdivision" means any county commission; municipality; county board of education; any instrumentality established by a county or municipality; any separate corporation or instrumentality established by one or more counties or municipalities, as permitted by law; or any public body charged by law with the performance of a government function or whose jurisdiction is coextensive with one or more counties or municipalities. "Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

EXCEPTION: The prohibition of this section does not apply where a vendor has contested any tax administered pursuant to chapter eleven of this code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

LICENSING: Vendors must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, West Virginia Insurance Commission, or any other state agencies or political subdivision. Furthermore, the vendor must provide all necessary releases to obtain information to enable the Director or spending unit to verify that the vendor is licensed and in good standing with the above entities.

CONFIDENTIALITY: The vendor agrees that he or she will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the agency's policies, procedures and rules. Vendors should visit **www.state.wv.us/admin/purchase/privacy** for the Notice of Agency Confidentiality Policies.

Under penalty of law for false swearing (West Virginia Code, §61-5-3), it is hereby certified that the vendor acknowledges the information in this said affidavit and are in compliance with the requirements as stated.

Vendor's Name: Meridian Medical Technologies Inc.

Authorized Signature: _____ Date: 5/11/07

WV-36a STATE OF WEST VIRGINIA

PURCHASING CONTINUATION SHEET

Buyer:	Page	Req. or P.O. No.:
RW-#22	003	BPH70353
Spending Unit:		

Vendor:

Requisition No.: BPH70353

ADDENDUM ACKNOWLEDGEMENT

I hereby acknowledge receipt of the following checked addendum(s) and have made the necessary revisions to my proposal, plans and/or specifications, etc.

Addendum No.'s:

No. 1 ✓

No. 2 ✓

No. 3 _____

No. 4 _____

No. 5 _____

I understand that failure to confirm the receipt of the addendum(s) **may be cause for rejection of bids.**

Signature

Meridian Medical Technologies Inc
Company

5/11/07
Date

EXHIBIT 10
Rev. 11/96

WV-36a STATE OF WEST VIRGINIA

PURCHASING CONTINUATION SHEET

Buyer:	Page	Req. or P.O. No.:
RW-#22	003	BPH70353

Spending Unit:

Vendor:

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No. 4 _____

No. 5 _____

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Signature

Meridian Medical Technologies Inc
Company

5/11/07
Date

EXHIBIT 10
Rev. 11/96

Duodote (atropine and pralidoxime chloride injection) Auto-Injector

Rx Only

Atropine 2.1 mg/0.7 mL
Pralidoxime Chloride 600 mg/2 mL

Sterile solutions for intramuscular use only

FOR USE IN NERVE AGENT AND INSECTICIDE POISONING ONLY

THE DUODOTE AUTO-INJECTOR SHOULD BE ADMINISTERED BY EMERGENCY MEDICAL SERVICES PERSONNEL WHO HAVE HAD ADEQUATE TRAINING IN THE RECOGNITION AND TREATMENT OF NERVE AGENT OR INSECTICIDE INTOXICATION.

CAUTION! INDIVIDUALS SHOULD NOT RELY SOLELY UPON ATROPINE AND PRALIDOXIME TO PROVIDE COMPLETE PROTECTION FROM CHEMICAL NERVE AGENTS AND INSECTICIDE POISONING.

PRIMARY PROTECTION AGAINST EXPOSURE TO CHEMICAL NERVE AGENTS AND INSECTICIDE POISONING IS THE WEARING OF PROTECTIVE GARMENTS INCLUDING MASKS DESIGNED SPECIFICALLY FOR THIS USE.

EVACUATION AND DECONTAMINATION PROCEDURES SHOULD BE UNDERTAKEN AS SOON AS POSSIBLE. MEDICAL PERSONNEL ASSISTING EVACUATED VICTIMS OF NERVE AGENT POISONING SHOULD AVOID CONTAMINATING THEMSELVES BY EXPOSURE TO THE VICTIM'S CLOTHING.

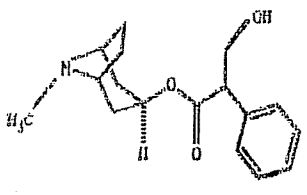
DESCRIPTION

Each prefilled Duodote Auto-Injector provides a single intramuscular dose of atropine and pralidoxime chloride in a self-contained unit, specifically designed for administration by emergency medical services personnel.

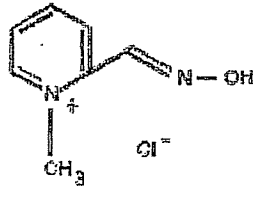
When activated, each Duodote Auto-Injector delivers the following:

- 2.1 mg of atropine in 0.7 mL of sterile, pyrogen-free solution containing 12.47 mg glycerin and not more than 2.8 mg phenol, citrate buffer, and Water for Injection. The pH range is 4.0 – 5.0.
- 600 mg of pralidoxime chloride in 2 mL of sterile, pyrogen-free solution containing 40 mg benzyl alcohol, 22.5 mg glycine, and Water for Injection. The pH is adjusted with hydrochloric acid. The pH range is 2.0 to 3.0.

Atropine, an anticholinergic agent (muscarinic antagonist), occurs as white crystals, usually needle-like, or as a white, crystalline powder. It is slightly soluble in water with a molecular weight of 289.38. Atropine, a naturally occurring belladonna alkaloid, is a racemic mixture of equal parts of d- and l-hyoscyamine, with activity due almost entirely to the levo isomer of the drug. Chemically, atropine is designated as 1αH,5αH-Tropan-3α-ol (±)-tropate. Its empirical formula is $C_{17}H_{23}NO_3$ and its structural formula is as follows.



atropine



pralidoxime chloride

Pralidoxime chloride, a cholinesterase reactivator, is an odorless, white to pale-yellow crystalline powder, freely soluble in water, with a molecular weight of 172.61. Chemically, pralidoxime chloride is designated as 2-formyl-l-methylpyridinium chloride oxime. Its empirical formula is $C_7H_9ClN_2O$ and its structural formula is indicated above.

CLINICAL PHARMACOLOGY

Mechanism of Action:

Atropine. Atropine competitively blocks the effects of acetylcholine, including excess acetylcholine due to organophosphorous poisoning, at muscarinic cholinergic receptors on smooth muscle, cardiac muscle, and secretory gland cells and in peripheral autonomic ganglia and the central nervous system.

Pralidoxime. Pralidoxime reactivates acetylcholinesterase which has been inactivated by phosphorylation due to an organophosphorous nerve agent or insecticide. However, pralidoxime does not reactivate acetylcholinesterase inactivated by all organophosphorous nerve agents (e.g., soman). Reactivated acetylcholinesterase hydrolyzes excess acetylcholine resulting from organophosphorous poisoning to help restore impaired cholinergic neural function. Reactivation is clinically important because only a small proportion of active acetylcholinesterase is needed to maintain vital functions. Pralidoxime cannot reactivate phosphorylated acetylcholinesterases that have undergone a further chemical reaction known as "aging".

Pharmacodynamics:

Atropine

Atropine reduces secretions in the mouth and respiratory passages, relieves airway constriction, and may reduce centrally-mediated respiratory paralysis. In severe organophosphorous poisoning, a fully atropinized patient may develop or continue to have respiratory failure and may require artificial respiration and suctioning of airway secretions. Atropine may cause thickening of secretions.

Atropine-induced parasympathetic inhibition may be preceded by a transient phase of stimulation, especially on the heart where small doses first slow the rate before characteristic tachycardia develops due to paralysis of vagal control. Atropine increases heart rate and reduces atrioventricular conduction time. Adequate atropine doses can prevent or abolish bradycardia or asystole produced by organophosphorous nerve agents.

Atropine may decrease the degree of partial heart block which can occur after organophosphorous poisoning. In some patients with complete heart block, atropine may accelerate the idioventricular rate; in others, the rate is stabilized. In some patients with conduction defects, atropine may cause paradoxical atrioventricular (A-V) block and nodal rhythm.

Atropine will not act on the neuromuscular junction and has no effect on muscle paralysis or weakness, fasciculations or tremors; pralidoxime is intended to treat these symptoms.

The Duodote Auto-Injector is intended as an initial treatment of the symptoms of organophosphorous insecticide or nerve agent poisonings; definitive medical care should be sought immediately.

The Duodote Auto-Injector should be administered as soon as symptoms of organophosphorous poisoning appear (e.g., usually tearing, excessive oral secretions, sneezing, muscle fasciculations). (See **DOSAGE AND ADMINISTRATION**)

INDIVIDUALS SHOULD NOT RELY SOLELY UPON ATROPINE AND PRALIDOXIME TO PROVIDE COMPLETE PROTECTION FROM CHEMICAL NERVE AGENTS AND INSECTICIDE POISONING.

PRIMARY PROTECTION AGAINST EXPOSURE TO CHEMICAL NERVE AGENTS AND INSECTICIDE POISONING IS THE WEARING OF PROTECTIVE GARMENTS INCLUDING MASKS DESIGNED SPECIFICALLY FOR THIS USE.

EVACUATION AND DECONTAMINATION PROCEDURES SHOULD BE UNDERTAKEN AS SOON AS POSSIBLE. MEDICAL PERSONNEL ASSISTING EVACUATED VICTIMS OF NERVE AGENT POISONING SHOULD AVOID CONTAMINATING THEMSELVES BY EXPOSURE TO THE VICTIM'S CLOTHING.

CONTRAINDICATIONS

In the presence of life-threatening poisoning by organophosphorous nerve agents or insecticides, there are no absolute contraindications to the use of Duodote.

WARNINGS

CAUTION! INDIVIDUALS SHOULD NOT RELY SOLELY UPON ATROPINE AND PRALIDOXIME TO PROVIDE COMPLETE PROTECTION FROM CHEMICAL NERVE AGENTS AND INSECTICIDE POISONING.

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When symptoms of poisoning are not severe, Duodote should be used with extreme caution in people with heart disease, arrhythmias, recent myocardial infarction, severe narrow angle glaucoma, pyloric stenosis, prostatic hypertrophy, significant renal insufficiency, chronic pulmonary disease, or hypersensitivity to any component of the product. Organophosphorous nerve agent poisoning often causes bradycardia but can be associated with a heart rate in the low, high, or normal range. Atropine increases heart rate and alleviates the bradycardia. In patients with a recent myocardial infarction and/or severe coronary artery disease, there is a possibility that atropine-induced tachycardia may cause ischemia, extend or initiate myocardial infarcts, and stimulate ventricular ectopy and fibrillation. In patients without cardiac disease, atropine administration is associated with the rare occurrence of ventricular ectopy or ventricular tachycardia. Conventional systemic doses may precipitate acute glaucoma in susceptible individuals, convert partial pyloric stenosis into complete pyloric obstruction, precipitate urinary retention in individuals with prostatic hypertrophy, or cause inspiration of bronchial secretions and formation of dangerous viscid plugs in individuals with chronic lung disease.

More than one dose of Duodote, to a maximum of three doses, may be necessary initially when symptoms are severe. **No more than three doses should be administered unless definitive medical care (e.g., hospitalization, respiratory support) is available.** (See **DOSAGE AND ADMINISTRATION**)

Severe difficulty in breathing after organophosphorous poisoning requires artificial respiration in addition to the use of Duodote.

A potential hazardous effect of atropine is inhibition of sweating which, in a warm environment or with exercise, can lead to hyperthermia and heat injury.

The elderly and children may be more susceptible to the effects of atropine.

PRECAUTIONS

General: The desperate condition of the organophosphorous-poisoned individual will generally mask such minor signs and symptoms of atropine and pralidoxime treatment as have been noted in normal subjects.

Because pralidoxime is excreted in the urine, a decrease in renal function will result in increased blood levels of the drug.

Duodote temporarily increases blood pressure, a known effect of pralidoxime. In a study of 24 healthy young adults administered a single dose of atropine and pralidoxime auto-injector intramuscularly (approximately 9 mg/kg pralidoxime chloride), diastolic blood pressure increased from baseline by 11 ± 14 mmHg (mean ± SD), and systolic blood pressure increased by 16 ± 19mm Hg, at 15 minutes post-dose. Blood pressures remained elevated at these approximate levels through one hour post-dose, began to decrease at two hours post-dose and were near pre-dose baseline at four hours post-dose. Intravenous pralidoxime doses of 30-45 mg/kg can produce moderate to marked increases in diastolic and systolic blood pressure.

Laboratory Tests: If organophosphorous poisoning is known or suspected, treatment should be instituted without waiting for confirmation of the diagnosis by laboratory tests. Red blood cell and plasma cholinesterase, and urinary paranitrophenol measurements (in the case of parathion exposure) may be helpful in confirming the diagnosis and following the course of the illness. However, miosis, rhinorrhea, and/or airway symptoms due to nerve agent vapor exposure may occur with normal cholinesterase levels. Also, normal red blood cell and plasma cholinesterase values vary widely by ethnic group, age, and whether the person is pregnant. A reduction in red blood cell cholinesterase concentration to below 50% of normal is strongly suggestive of organophosphorous ester poisoning.

Drug Interactions:

When atropine and pralidoxime are used together, pralidoxime may potentiate the effect of atropine. When used in combination, signs of atropinization (flushing, mydriasis, tachycardia, dryness of the mouth and nose) may occur earlier than might be expected when atropine is used alone.

The following precautions should be kept in mind in the treatment of anticholinesterase poisoning, although they do not bear directly on the use of atropine and pralidoxime.

- Barbiturates are potentiated by the anticholinesterases; therefore, barbiturates should be used cautiously in the treatment of convulsions.
- Morphine, theophylline, aminophylline, succinylcholine, reserpine, and phenothiazine-type tranquilizers should be avoided in treating personnel with organophosphorus poisoning.
- Succinylcholine and mivacurium are metabolized by cholinesterases. Since pralidoxime reactivates cholinesterases, use of pralidoxime in organophosphorous poisoning may accelerate reversal of the neuromuscular blocking effects of succinylcholine and mivacurium.

Drug-drug interaction potential involving cytochrome P450 isozymes has not been studied.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Duodote is indicated for short-term emergency use only, and no adequate studies regarding the potential of atropine or pralidoxime chloride for carcinogenesis or mutagenesis have been conducted.

Impairment of Fertility:
In studies in which male rats were orally administered atropine (62.5 to 125 mg/kg) for one week prior to mating and throughout a 5-day mating period with untreated females, a dose-related decrease in fertility was observed. A no-effect dose for male reproductive toxicity was not established. The low-effect dose was 290 times (on a mg/m² basis) the dose of atropine in a single application of Duodote (2.1 mg).

Fertility studies of atropine in females or of pralidoxime in males or females have not been conducted.

Pregnancy:
Pregnancy Category C: Adequate animal reproduction studies have not been conducted with atropine, pralidoxime, or the combination. It is not known whether pralidoxime or atropine can cause fetal harm when administered to a pregnant woman or if they can affect reproductive capacity. Atropine readily crosses the

Physostigmine, given as an atropine antidote by slow intravenous injection of 1 to 4 mg (0.5 to 1.0 mg in children) rapidly abolishes delirium and coma caused by large doses of atropine. Since physostigmine has a short duration of action, the patient may again lapse into coma after one or two hours, and require repeated doses. Neostigmine, pilocarpine, and methacholine are of little benefit, since they do not penetrate the blood-brain barrier.

Pralidoxime-induced hypertension has been treated by administering phentolamine 5 mg intravenously, repeated if necessary due to phentolamine's short duration of action. In the absence of substantial clinical data regarding use of phentolamine to treat pralidoxime-induced hypertension, consider slow infusion to avoid precipitous corrections in blood pressure.

DOSAGE AND ADMINISTRATION

THE DUODOTE AUTO-INJECTOR SHOULD BE ADMINISTERED BY EMERGENCY MEDICAL SERVICES PERSONNEL WHO HAVE HAD ADEQUATE TRAINING IN THE RECOGNITION AND TREATMENT OF NERVE AGENT OR INSECTICIDE INTOXICATION.

CAUTION! INDIVIDUALS SHOULD NOT RELY SOLELY UPON ATROPINE AND PRALIDOXIME TO PROVIDE COMPLETE PROTECTION FROM CHEMICAL NERVE AGENTS AND INSECTICIDE POISONING.

PRIMARY PROTECTION AGAINST EXPOSURE TO CHEMICAL NERVE AGENTS AND INSECTICIDE POISONING IS THE WEARING OF PROTECTIVE GARMENTS INCLUDING MASKS DESIGNED SPECIFICALLY FOR THIS USE.

EVACUATION AND DECONTAMINATION PROCEDURES SHOULD BE UNDERTAKEN AS SOON AS POSSIBLE. MEDICAL PERSONNEL ASSISTING EVACUATED VICTIMS OF NERVE AGENT POISONING SHOULD AVOID CONTAMINATING THEMSELVES BY EXPOSURE TO THE VICTIM'S CLOTHING.

Duodote is indicated for the treatment of poisoning by organophosphorous nerve agents as well as organophosphorous insecticides. Duodote should only be administered to patients experiencing symptoms of organophosphorous poisoning in a situation where exposure is known or suspected. Duodote should be administered as soon as symptoms of organophosphorous poisoning appear.

The Duodote Auto-Injector is intended as an initial treatment of the symptoms of organophosphorous insecticide or nerve agent poisonings; definitive medical care should be sought immediately.

NERVE AGENT AND INSECTICIDE POISONING SYMPTOMS

Common symptoms of organophosphorous exposure are listed below. Individuals may not have all symptoms:

MILD SYMPTOMS	SEVERE SYMPTOMS
-Blurred vision, miosis	-Strange or confused behavior
-Excessive, unexplained teary eyes	-Severe difficulty breathing or copious secretions from lungs/airway
-Excessive, unexplained runny nose	-Severe muscular twitching and general weakness
-Increased salivation such as sudden drooling	-Involuntary urination and defecation
-Chest tightness or difficulty breathing	-Convulsions
-Tremors throughout the body or muscular twitching	-Unconsciousness
-Nausea and/or vomiting	
-Unexplained wheezing, coughing or increased airway secretions	
-Acute onset of stomach cramps	
-Tachycardia or bradycardia	

Three (3) Duodote Auto-Injectors should be available for use in each patient (including emergency medical services personnel) at risk for organophosphorous poisoning; one (1) for mild symptoms plus two (2) more for severe symptoms as described below. Each Duodote Auto-Injector delivers atropine 2.1 mg plus pralidoxime chloride 600 mg.

TREATMENT OF MILD SYMPTOMS

FIRST DOSE: In the situation of known or suspected organophosphorous poisoning, administer one (1) Duodote injection into the mid-lateral thigh if the patient experiences two or more MILD symptoms of nerve gas or insecticide exposure.

Emergency medical services personnel with mild symptoms may self-administer a single dose of Duodote.

Wait 10 to 15 minutes for Duodote to take effect. If, after 10 to 15 minutes, the patient does not develop any of the SEVERE symptoms listed above, no additional Duodote injections are recommended, but definitive medical care should ordinarily be sought immediately. For emergency medical services personnel who have self-administered Duodote, an individual decision will need to be made to determine their capacity to continue to provide emergency care.

ADDITIONAL DOSES: If, at any time after the first dose, the patient develops any of the **SEVERE** symptoms listed above, administer two (2) additional Duodote injections in rapid succession, and immediately seek definitive medical care.

TREATMENT OF SEVERE SYMPTOMS

If a patient has any of the **SEVERE** symptoms listed above, immediately administer **three** (3) Duodote injections into the patient's mid-lateral thigh in rapid succession, and immediately seek definitive medical care.

No more than three doses of Duodote should be administered unless definitive medical care (e.g., hospitalization, respiratory support) is available.

Emergency care of the severely poisoned individual should include removal of oral and bronchial secretions, maintenance of a patent airway, supplemental oxygen, and, if necessary, artificial ventilation.

An anticonvulsant such as diazepam may be administered to treat convulsions if suspected in the unconscious individual. The effects of nerve agents and some insecticides can mask the motor signs of a seizure.

Close supervision of all severely poisoned patients is indicated for at least 48 to 72 hours.

INSTRUCTIONS FOR THE USE OF THE DUODOTE AUTO-INJECTOR
(Also see the Illustrated Instruction Sheet for Emergency Medical Personnel)

IMPORTANT: Do Not Remove Gray Safety Release until ready to use.

CAUTION: Never touch the Green Tip (Needle End)!

1) Tear open the plastic pouch at any of the notches. Remove the Duodote Auto-Injector from the pouch.

2) Place the Duodote Auto-Injector in your dominant hand. (If you are right-handed, your right hand is dominant.) Firmly grasp the center of the Duodote Auto-Injector with the Green Tip (needle end) pointing down.

3) With your other hand, pull off the Gray Safety Release. The Duodote Auto-Injector is now ready to be administered.

4) The injection site is the mid-outer thigh area. The Duodote Auto-Injector can inject through clothing. **However, make sure pockets at the injection site are empty.**

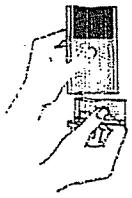
5) Swing and firmly push the Green Tip straight down (a 90° angle) against the mid-outer thigh. Continue to firmly push until you feel the Duodote Auto-Injector trigger.
IMPORTANT: After the Auto-Injector triggers, hold the Duodote Auto-Injector firmly in place against the injection site for approximately 10 seconds.

6) Remove the Duodote Auto-Injector from the thigh and look at the Green Tip. If the needle is visible, the drug has been administered. If the needle is not visible, check to be sure the Gray Safety Release has been removed, and then repeat above steps beginning with Step 4, but push harder in Step 5.

INSTRUCTIONS FOR THE USE OF THE DUODOTE AUTO-INJECTOR
IMPORTANT: Do Not Remove Gray Safety Release until ready to use.

CAUTION: Never touch the Green Tip (Needle End)!

1) Tear open the plastic pouch at any of the notches. Remove the Duodote Auto-Injector from the pouch.



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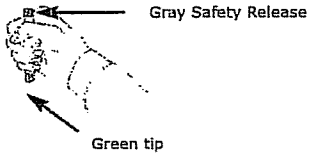

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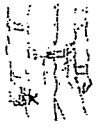

IMPORTANT: After the Auto-Injector triggers, hold the Duodote Auto-Injector firmly in place against the injection site for approximately 10 seconds.

6) Remove the Duodote Auto-Injector from the thigh and look at Green Tip. If the needle is visible, the drug has been administered. If the needle is not visible, check to be sure the Gray Safety Release has been removed, and then repeat above steps beginning with Step 4, but push harder in Step 5.

9) *Immediately move yourself and the patient away from the contaminated area and seek definitive medical care for the patient.*

HOW SUPPLIED

Each Duodote Auto-Injector contains a sterile solution of atropine (2.1 mg/0.7 mL) and a sterile solution of pralidoxime chloride (600 mg/2 mL) in two separate internal chambers. When activated, the Duodote Auto-Injector sequentially administers both drugs intramuscularly through a single needle in one injection.

Duodote is available in a single unit carton, NDC-11704-620-01.

Each Duodote is supplied in a pouch that provides protection from light.

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [See USP Controlled Room Temperature]. Contains no latex. Keep from freezing. Protect from light.

Manufactured by:
Meridian Medical Technologies™, Inc.
Columbia, MD 21046

A wholly owned subsidiary of King Pharmaceuticals®, Inc.
1-800-776-3637

Instruction Sheet for Emergency Medical Services Personnel

THE DUODOTE AUTO-INJECTOR SHOULD BE ADMINISTERED BY EMERGENCY MEDICAL SERVICES PERSONNEL WHO HAVE HAD ADEQUATE TRAINING IN THE RECOGNITION AND TREATMENT OF NERVE AGENT OR INSECTICIDE INTOXICATION.

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NERVE AGENT AND INSECTICIDE POISONING SYMPTOMS

Common symptoms of organophosphorous exposure are listed below. Individuals may not have all symptoms:

MILD SYMPTOMS
-Blurred vision, miosis
-Excessive, unexplained teary eyes
-Excessive, unexplained runny nose
-Increased salivation such as sudden drooling
-Chest tightness or difficulty breathing
-Tremors throughout the body or muscular twitching
-Nausea and/or vomiting
-Unexplained wheezing, coughing or increased airway secretions
-Acute onset of stomach cramps
-Tachycardia or bradycardia

SEVERE SYMPTOMS
-Strange or confused behavior
-Severe difficulty breathing or copious secretions from lungs/airway
-Severe muscular twitching and general weakness
-Involuntary urination and defecation
-Convulsions
-Unconsciousness

TREATMENT OF MILD SYMPTOMS

FIRST DOSE: In the situation of known or suspected organophosphorous poisoning, administer one (1) Duodote injection into the mid-lateral thigh if the patient experiences two or more MILD symptoms of nerve gas or insecticide exposure.

Emergency medical services personnel with mild symptoms may self-administer a single dose of Duodote.

Wait 10 to 15 minutes for Duodote to take effect. If, after 10 to 15 minutes, the patient does not develop any of the SEVERE symptoms listed above, no additional Duodote injections are recommended, but definitive medical care should ordinarily be sought immediately. For emergency medical services personnel who have self-administered Duodote, an individual decision will need to be made to determine their capacity to continue to provide emergency care.

ADDITIONAL DOSES: If, at any time after the first dose, the patient develops any of the **SEVERE** symptoms listed above, administer two (2) additional Duodote injections in rapid succession, and immediately seek definitive medical care.

TREATMENT OF SEVERE SYMPTOMS

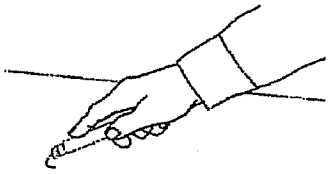
If a patient has any of the **SEVERE** symptoms listed above, immediately administer **three** (3) Duodote injections into the patient's mid-lateral thigh in rapid succession, and immediately seek definitive medical care.

No more than three doses of Duodote should be administered unless definitive medical care (e.g., hospitalization, respiratory support) is available.

Emergency care of the severely poisoned individual should include removal of oral and bronchial secretions, maintenance of a patent airway, supplemental oxygen, and, if necessary, artificial ventilation.

An anticonvulsant such as diazepam may be administered to treat convulsions if suspected in the unconscious individual. The effects of nerve agents and some insecticides can mask the motor signs of a seizure.

Close supervision of all severely poisoned patients is indicated for at least 48 to 72 hours.



8) Put the used Duodote Auto-Injector back into the plastic pouch, if available. Leave used Duodote Auto-Injector(s) with the patient to allow other medical personnel to see the number of Duodote Auto-Injector(s) administered.

9) Immediately move yourself and the patient away from the contaminated area and seek definitive medical care for the patient.

Pralidoxime Chloride

Pralidoxime chloride has its most critical effect in relieving respiratory muscle paralysis. Because pralidoxime is less effective in relieving depression of the respiratory center, atropine is always required concomitantly to block the effect of accumulated acetylcholine at this site. Pralidoxime has a minor role in relieving muscarinic signs and symptoms, such as salivation or bronchospasm.

Pharmacokinetics:

Atropine

Atropine is rapidly and well absorbed after intramuscular administration. Atropine disappears rapidly from the blood and is distributed throughout the various body tissues and fluids. Single dose Duodote pharmacokinetic and pharmacodynamic data for atropine are shown in Figure 1. The intramuscular injection site was the antero-lateral thigh.

Mean atropine plasma concentrations shown in Figure 1 indicate a plateau beginning at about 5 minutes postdose and extending through 60 minutes postdose.

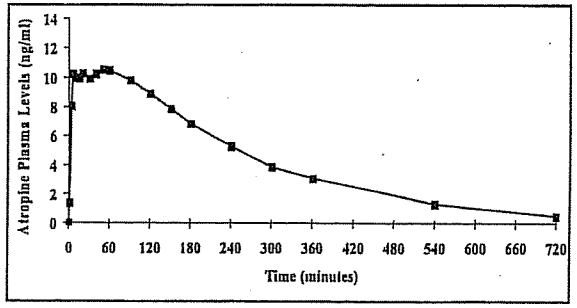


Figure 1. Mean atropine plasma concentrations after a single Duodote intramuscular injection which delivers 2.1 mg of atropine and 600 mg pralidoxime chloride, n=24 healthy subjects [men (n=12), women (n=12)].

The C_{max}, T_{max}, and $T_{\frac{1}{2}}$ of atropine given intramuscularly by Duodote delivery system was 13 ± 3 ng/mL, 31± 30 minutes, and 2.4 ± 0.3 hours, respectively. The protein binding of atropine is 14 - 22% in plasma. Duodote $AUC_{0-\infty}$ and C_{max} values for atropine are 15% higher in females than males. The half-life of atropine is approximately 20 minutes shorter in females than males.

In healthy volunteers, approximately 50-60% of intravenous atropine is excreted in the urine as unchanged drug with approximately 17-28% renally eliminated in the first 100 minutes. Noratropine, atropine N-oxide, tropic acid, and tropine are the reported metabolites in the urine. Much of the drug is destroyed by enzymatic hydrolysis, particularly in the liver. Half-life of intravenous atropine is 3.0 ± 0.9 hours in adults and 10.0 ± 7.3 hours in geriatric patients (65-75 years of age).

Atropine pharmacokinetics have not been evaluated in patients with renal or hepatic impairment. Since atropine is approximately equally metabolized and renally excreted, atropine elimination in patients with mild to moderate renal impairment might not differ substantially from that of healthy subjects. Patients with severe renal or hepatic impairment may eliminate atropine more slowly and might require smaller, and/or less frequent, doses after initial atropinization.

Pralidoxime Chloride

Pralidoxime chloride is rapidly absorbed after intramuscular injection. Duodote single dose pharmacokinetic data for pralidoxime chloride 600 mg are provided in Figure 2. These data are derived from the bioavailability study described above for atropine pharmacokinetics.

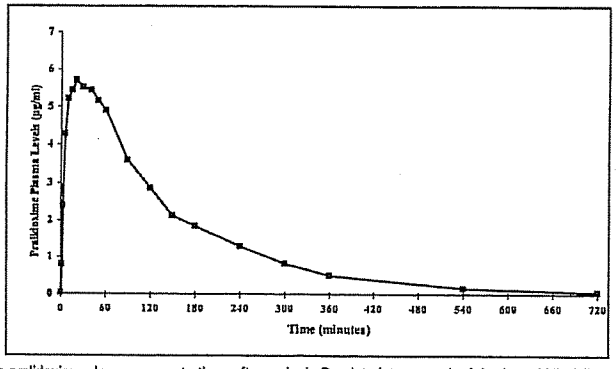


Figure 2. Mean pralidoxime plasma concentrations after a single Duodote intramuscular injection which delivers 2.1 mg of atropine and 600 mg pralidoxime chloride, n=24 healthy subjects.

The C_{max}, T_{max}, and $T_{\frac{1}{2}}$ of pralidoxime following 600 mg pralidoxime given intramuscularly by Duodote delivery system was 7 ± 3 ng/mL, 28 ± 15 minutes, and 2 ± 1 hour, respectively. In the same study, a single Duodote injection produced a mean C_{max} for pralidoxime about 36% higher in females than males. T_{max} is 23 minutes in females and 32 minutes in males. Pralidoxime half-life in males and females are 153 and 107 minutes, respectively.

In healthy volunteers, approximately 72-94% of intravenous pralidoxime is excreted unchanged in the urine, about 57-70% in the first 30 minutes, partly as metabolite. Pralidoxime is subject to active renal secretion. Elimination of pralidoxime can be reduced by the concurrent administration of organic bases, such as thiamine, but not organic acids, and can be altered by urine pH. Pralidoxime distributes into tissues and is not appreciably bound to serum protein.

Pralidoxime pharmacokinetics have not been evaluated in patients with renal or hepatic impairment. Since pralidoxime is primarily excreted in the urine, a decrease in renal function will result in increased blood levels of the drug. Thus, dose reduction should be considered for patients with renal insufficiency.

INDICATIONS AND USAGE

Duodote is indicated for the treatment of poisoning by organophosphorous nerve agents as well as organophosphorous insecticides.

The Duodote Auto-Injector should be administered by emergency medical services personnel who have had adequate training in the recognition and treatment of nerve agent or insecticide intoxication.

are excreted in human milk, caution should be exercised when Duodote is administered to a nursing woman.

Pediatric Use: Safety and effectiveness of Duodote in pediatric patients have not been established.

ADVERSE REACTIONS

Muscle tightness and sometimes pain may occur at the injection site.

Atropine

The most common side effects of atropine can be attributed to its antimuscarinic action. These include dryness of the mouth, blurred vision, dry eyes, photophobia, confusion, headache, dizziness, tachycardia, palpitations, flushing, urinary hesitancy or retention, constipation, abdominal pain, abdominal distention, nausea and vomiting, loss of libido, and impotence. Anhidrosis may produce heat intolerance and impairment of temperature regulation in a hot environment. Dysphagia, paralytic ileus, and acute angle closure glaucoma, maculopapular rash, petechial rash, and scarlatiniform rash have also been reported.

Larger or toxic doses may produce such central effects as restlessness, tremor, fatigue, locomotor difficulties, delirium followed by hallucinations, depression, and, ultimately medullary paralysis and death. Large doses can also lead to circulatory collapse. In such cases, blood pressure declines and death due to respiratory failure may ensue following paralysis and coma.

Cardiovascular adverse events reported in the literature for atropine include, but are not limited to, sinus tachycardia, palpitations, premature ventricular contractions, atrial flutter, atrial fibrillation, ventricular flutter, ventricular fibrillation, cardiac syncope, asystole, and myocardial infarction. (See PRECAUTIONS)

Hypersensitivity reactions will occasionally occur, are usually seen as skin rashes, and may progress to exfoliation. Anaphylactic reaction and laryngospasm are rare.

Pralidoxime Chloride

Pralidoxime can cause blurred vision, diplopia and impaired accommodation, dizziness, headache, drowsiness, nausea, tachycardia, increased systolic and diastolic blood pressure, muscular weakness, dry mouth, emesis, rash, dry skin, hyperventilation, decreased renal function, and decreased sweating when given parenterally to normal volunteers who have not been exposed to anticholinesterase poisons.

In several cases of organophosphorous poisoning, excitement and manic behavior have occurred immediately following recovery of consciousness, in either the presence or absence of pralidoxime administration. However, similar behavior has not been reported in subjects given pralidoxime in the absence of organophosphorous poisoning.

Elevations in SGOT and/or SGPT enzyme levels were observed in 1 of 6 normal volunteers given 1200 mg of pralidoxime intramuscularly, and in 4 of 6 volunteers given 1800 mg intramuscularly. Levels returned to normal in about two weeks. Transient elevations in creatine kinase were observed in all normal volunteers given the drug.

Atropine and Pralidoxime Chloride

When atropine and pralidoxime are used together, the signs of atropinization may occur earlier than might be expected when atropine is used alone.

INADVERTANT INJECTION

The Duodote Auto-Injector should be administered by emergency medical services personnel to treat organophosphorous poisoning. However, an injection might be given by mistake to someone who is not poisoned.

Studies have been conducted to evaluate the effect of atropine and pralidoxime on individuals in the absence of poisoning.

> Atropine 2 mg IM, roughly the equivalent of one Duodote Auto-Injector, when given to healthy male volunteers, is associated with minimal effects on visual, motor, and mental functions, though unsteadiness walking and difficulty concentrating may occur. Atropine reduces body sweating and increases body temperature, particularly with exercise and under hot conditions.
>
> Atropine 4 mg IM, roughly the equivalent of two Duodote Auto-Injectors, when given to healthy male volunteers, is associated with impaired visual acuity, visual near point accommodation, logical reasoning, digital recall, learning, and cognitive reaction time. Ability to read is reduced or lost. Subjects are unsteady and need to concentrate on walking. These effects begin about 15 minutes to one hour or more post-dose.
>
> Atropine 6 mg IM, roughly the equivalent of three Duodote Auto-Injectors, when given to healthy male volunteers, is associated with the effects described above plus additional central effects including poor coordination, poor attention span, and visual hallucinations (colored flashes) in many subjects. Frank visual hallucinations, auditory hallucinations, disorientation, and ataxia occur in some subjects. Skilled and labor-intense tasks are performed more slowly and less efficiently. Decision making takes longer and is sometimes impaired.

It is unclear if the results of the above studies can be extrapolated to other populations. In the elderly and patients with co-morbid conditions, the effects of ≥ 2 mg atropine on the ability to see, walk and think properly are unstudied; effects may be greater in susceptible populations.

> Symptoms of pralidoxime overdose may include: dizziness, blurred vision, diplopia, headache, impaired accommodation, nausea, and slight tachycardia. Transient hypertension due to pralidoxime may last several hours.

Patients who are mistakenly injected with Duodote should avoid potentially dangerous overheating, avoid vigorous physical activity, and seek medical attention as soon as feasible.

OVERDOSAGE

Symptoms:

Atropine

Manifestations of atropine overdose are dose-related and include flushing, dry skin and mucous membranes, tachycardia, widely dilated pupils that are poorly responsive to light, blurred vision, and fever (which can sometimes be dangerously elevated). Locomotor difficulties, disorientation, hallucinations, delirium, confusion, agitation, coma, and central depression can occur and may last 48 hours or longer. In instances of severe atropine intoxication, respiratory depression, coma, circulatory collapse, and death may occur.

The fatal dose of atropine is unknown. In the treatment of organophosphorous poisoning, doses as high as 1000 mg have been given. The few deaths in adults reported in the literature were generally seen using typical clinical doses of atropine often in the setting of bradycardia associated with an acute myocardial infarction, or with larger doses, due to overheating in a setting of vigorous physical activity in a hot environment.

Pralidoxime

It may be difficult to differentiate some of the side effects due to pralidoxime from those due to organophosphorous poisoning. Symptoms of pralidoxime overdose may include: dizziness, blurred vision, diplopia, headache, impaired accommodation, nausea, and slight tachycardia. Transient hypertension due to pralidoxime may last several hours.

Treatment:

For atropine overdose, supportive treatment should be administered. If respiration is depressed, artificial respiration with oxygen is necessary. Ice bags, a hypothermia blanket, or other methods of cooling may be required to reduce atropine-induced fever, especially in children. Catheterization may be necessary if urinary retention occurs. Since atropine elimination takes place through the kidney, urinary output must be maintained and increased if possible; intravenous fluids may be indicated. Because of atropine-induced photophobia, the room should be darkened.

A short-acting barbiturate or diazepam may be needed to control marked excitement and convulsions. However, large doses for sedation should be avoided because central depressant action may coincide with the depression occurring late in severe atropine poisoning. Central stimulants are not recommended.