



Guidelines and Injection Instructions for DuoDoteTM Auto-Injector

Preparing for the unexpected.TM

DuoDote™ Has Replaced the Mark I™ Kit
Delivers the same protection in a single auto-injector

Product Name:

DuoDote™ Auto-Injector¹



Mark I™ Kit^{2,3}



Active Ingredients:

- 2.1 mg atropine
- 600 mg pralidoxime chloride

- 2 mg atropine
- 600 mg pralidoxime chloride

Delivery Mechanism:

1 auto-injector featuring dual-chamber technology

2 auto-injectors, each with a single traditional chamber

Steps to Administer:

Simple administration with just 1 injection

Additional steps required – 2 separate injections

Overall Dimensions:

6" x 1" x 1"

6" x 1.5" x 1"

Shelf Life:

4 years

5 years

Packaging:

Chemically hardened pouch

Foam pouch

What Is DuoDoteTM ?

- Developed by Meridian Medical TechnologiesTM as a streamlined, easy-to-use replacement for the **Mark I Kit**
- FDA approved for Emergency Medical Services (EMS) use in the treatment of organophosphorus nerve agent and organophosphorus insecticide poisoning
- Contains two antidotes in 1 auto-injector
 - 2.1 mg of atropine in a 0.7-mL solution
 - 600 mg of pralidoxime chloride in a 2_{TM}mL solution
- Features next-generation BinaJect delivery technology
 - 2 antidotes delivered sequentially into separate areas of the muscle
 - Easy to use: only 1 injection with 1 needle



What Is DuoDoteTM ? (contd)

■ Indications

- The DuoDoteTM Auto-Injector (atropine and pralidoxime chloride injection) is indicated for the treatment of poisoning by organophosphorus nerve agents as well as organophosphorus insecticides
- The DuoDoteTM 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
- **The DuoDoteTM Auto-Injector is intended as an initial treatment of the symptoms of organophosphorus insecticide or nerve agent poisoning; definitive medical care should be sought immediately**
- The DuoDoteTM Auto-Injector should be administered as soon as symptoms of organophosphorus poisoning appear

Organophosphorus Poisoning: What Are the Symptoms?

4,5

- ~~Mild~~ symptoms
 - Blurred vision, miosis (excessive constriction of the pupils)
 - 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 (abnormally fast or slow heartbeat)



Organophosphorus Poisoning: What Are the Symptoms? (contd)

- ~~Severe~~ symptoms^{4,5}
 - Strange or confused behavior
 - Severe difficulty breathing or copious secretions from lungs/airway
 - Severe muscular twitching and general weakness
 - Involuntary urination and defecation
 - Convulsions
 - Loss of consciousness
 - Respiratory arrest (possibly leading to death)



Organophosphorus Poisoning: What Are the Symptoms? (contd)

- A quick-reference mnemonic for use in the field is

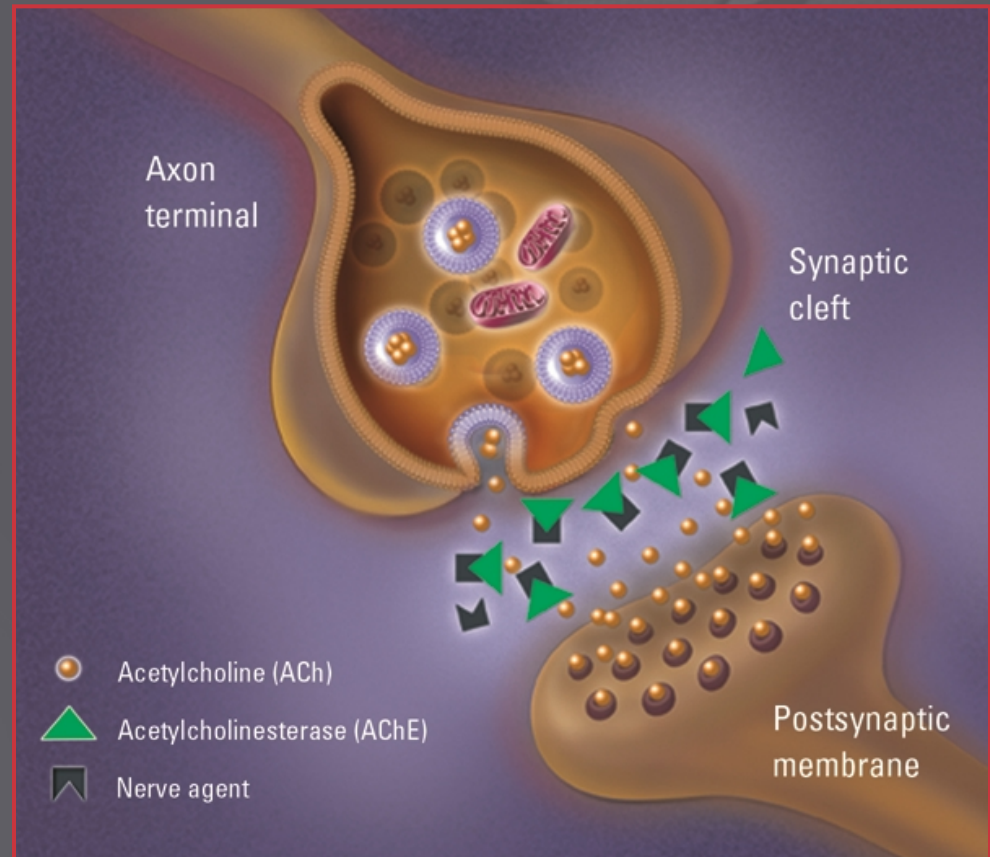
OBSERVE

- **O**thers affected suddenly
- **B**ody tremors/twitching
- **S**alivation
- **E**ye tearing
- **R**estricted breathing
- **V**omiting
- **E**xcessive sweating



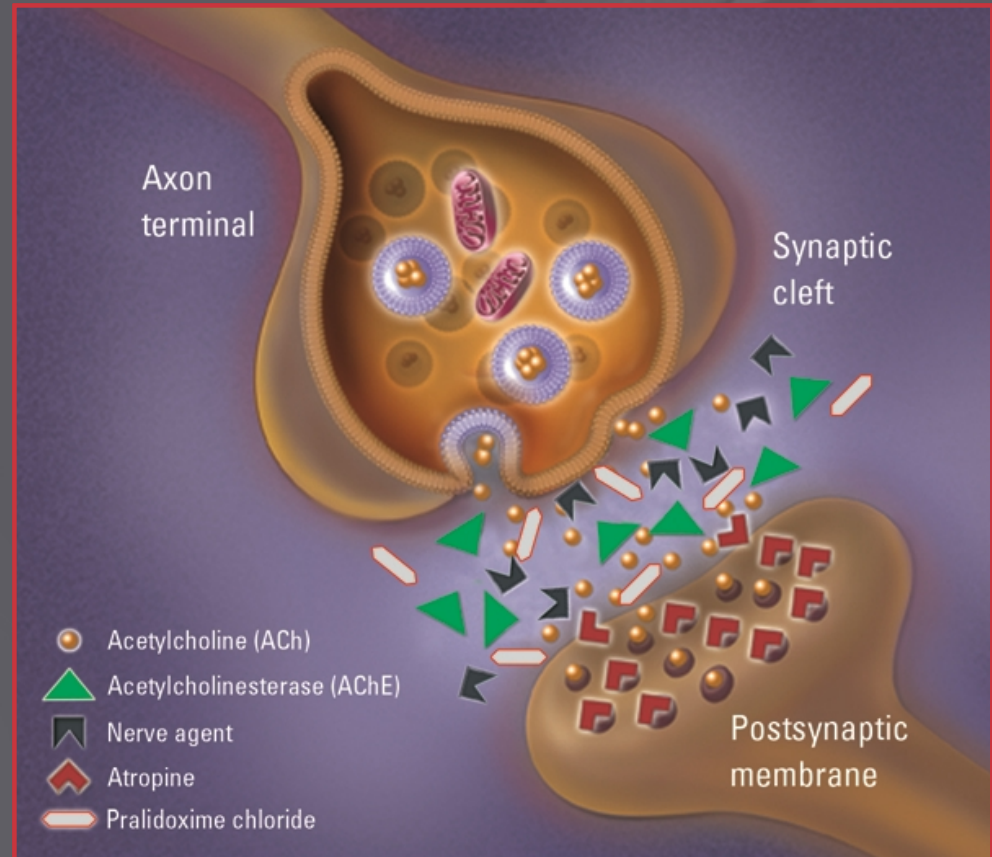
Where Does DuoDote™ Work?

- Effects of organophosphorus poisoning
 - Chemical nerve agents and organophosphorus insecticides cause an excess buildup of acetylcholine (ACh), a neurotransmitter
 - This buildup occurs when the activity of an enzyme called acetylcholinesterase (AChE) is blocked by the nerve agent
 - Blocking AChE results in overstimulation of cholinergic nervous pathways
 - There are 2 types of ACh receptors: ~~muscarinic~~ muscarinic receptors affect breathing and gastrointestinal functions, while ~~nicotinic~~ nicotinic receptors affect vascular function and muscle movement



How Does DuoDote™ Work?

- Complementary actions
 - Atropine blocks ACh on the postsynaptic (downstream) side of synapses at muscarinic cholinergic receptors in multiple organ systems, thereby reducing cholinergic overstimulation
 - Pralidoxime chloride reactivates the AChE enzyme, allowing it to resume its function of moderating the activity of ACh once again



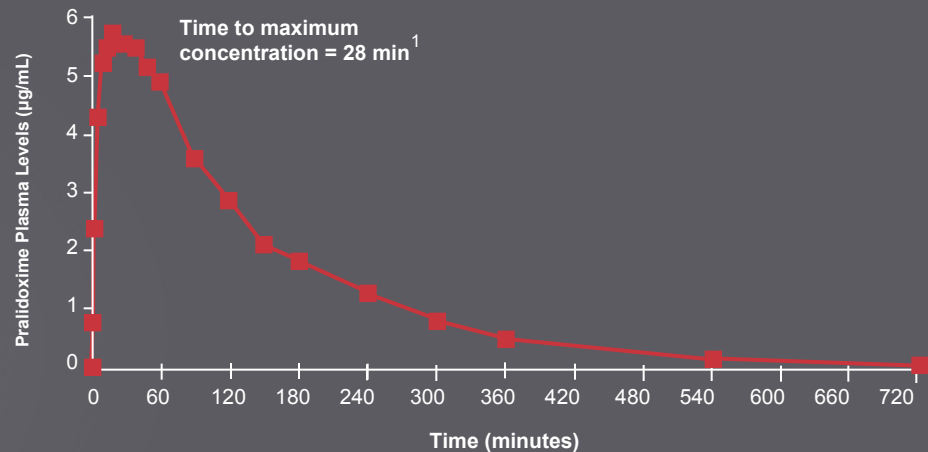
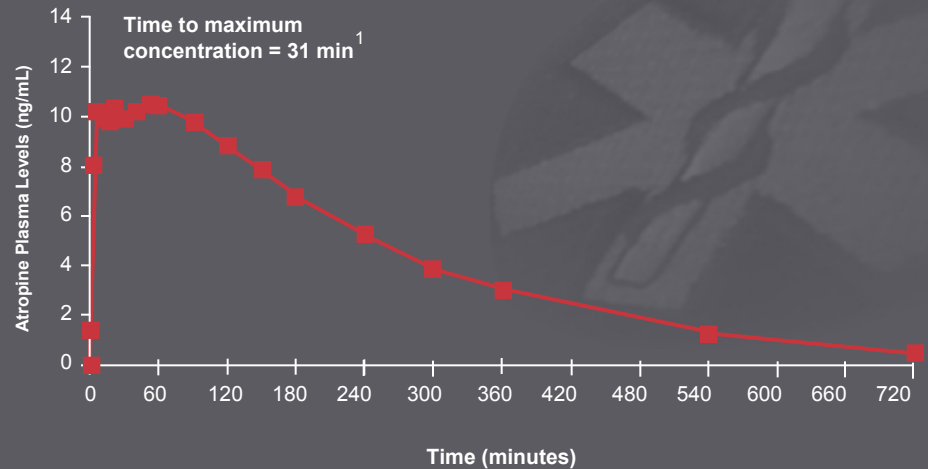
TM

How Does DuoDoteTM Work? (contd)

- The two antidotes delivered by the DuoDoteTM Auto-Injector counteract the excessive stimulation of the cholinergic nervous system in different but complementary ways
- Effects of atropine
 - Reduces secretions in the mouth and respiratory passages
 - Relieves airway constriction and increases heart rate
 - No effect on muscle paralysis or weakness
- Effects of pralidoxime chloride
 - Relieves respiratory muscle paralysis
 - Reduces muscle weakness throughout the body

How Quickly Does DuoDoteTM Work?

- After injection, atropine and pralidoxime chloride begin counteracting the effects of organophosphorus poisoning within about 10 minutes
- Both antidotes reach their peak concentrations in the bloodstream within about 30 minutes



Guidelines for Administering DuoDote

- For **mild** symptoms of organophosphorus poisoning
 - **FIRST DOSE:** In the situation of known or suspected organophosphorus poisoning, administer one DuoDote™ injection into the mid-outer thigh if the patient experiences two or more MILD symptoms of nerve gas or insecticide exposure
 - EMS 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 **SEVERE** symptoms, no additional DuoDote™ injections are recommended, but definitive medical care should ordinarily be sought immediately. For EMS 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 **SEVERE** symptoms, administer two additional DuoDote™ injections in rapid succession, and immediately seek definitive medical care

Guidelines for Administering DuoDote™ (contd)

- For ~~severe~~ symptoms of organophosphorus poisoning
 - If a patientTM has any **SEVERE** symptoms of organophosphorus poisoning, immediately administer **three** DuoDote™ injections into the patient's mid-outer thigh in rapid succession, and immediately seek definitive medical care
 - **No more than 3 doses of DuoDote™ should be administered unless definitive medical care (eg, 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

^a Limit of 3 doses is specific to the pralidoxime component of DuoDote™. If necessary, additional doses of AtroPer® Auto-Injector (atropine) can be administered if the 3 doses of DuoDote™ do not produce an adequate response.²

^b Diazepam is recommended in addition to DuoDote™ if symptoms include convulsions. Please see full Prescribing Information for Diazepam Auto-Injector (C-IV).⁶
[\[http://www.meridianmeds.com/pdf/Diazepam_Pack_Insert.pdf\]](http://www.meridianmeds.com/pdf/Diazepam_Pack_Insert.pdf)



DuoDote™ Injection Instructions

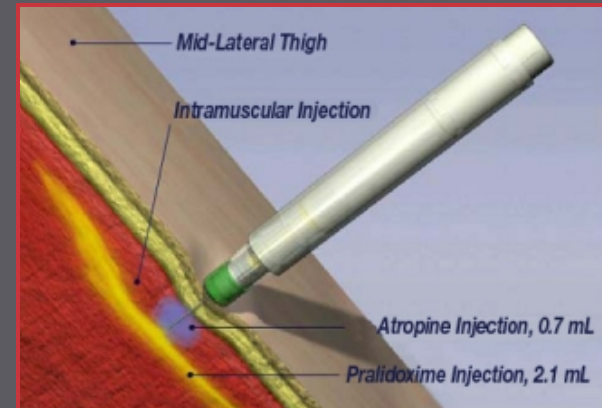
■ Before injecting

- Tear open plastic pouch at any of the notches, and remove the DuoDote™ Auto-Injector™
- Place DuoDote™ in your dominant hand and firmly grasp it, with the **Green Tip** pointing downward
- With your other hand, pull off the Gray Safety Release, taking care never to touch the **Green Tip**
- Keep fingers clear of both ends of the auto-injector
- You are now ready to inject



DuoDote™ Injection Instructions (contd)

- Select site and inject
 - The injection site is the mid-outer thigh area. You can inject through clothing, but make sure that pockets are empty
 - Swing and firmly push **Green Tip** straight down (at a 90° angle) against mid-outer thigh, continuing to push firmly until you feel the auto-injector trigger
 - After the DuoDote™ Auto-Injector triggers, hold it firmly in place against the injection site for 10 seconds



DuoDote™ Auto-Injector 1 Injection Instructions (contd)

After injecting

- Remove the DuoDote™ Auto-Injector from thigh and inspect the **Green Tip**; if the needle is visible, then the injection was successful
- If the needle is not visible, make sure the Gray Safety Release is removed and repeat the preceding injection steps
- Push the exposed needle against a hard surface until it bends back, then put the used auto-injector back in the plastic pouch
- Keep used auto-injector(s) with the patient so other medical personnel will be aware of how many injections were administered
- Immediately move away from the contaminated area, decontaminate skin and clothing, and seek definitive medical treatment



Important Safety Information

The DuoDote™ Auto-Injector is intended as an initial treatment of the symptoms of organophosphorus insecticide or nerve agent poisonings; definitive medical care should be sought immediately. The DuoDote™ Auto-Injector should be administered by EMS personnel who have had adequate training in the recognition and treatment of nerve agent or insecticide intoxication.

Individuals should not rely solely upon agents such as 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.**

In the presence of life-threatening poisoning by organophosphorus nerve agents or insecticides, there are no absolute contraindications to the use of the DuoDote™ Auto-Injector. When symptoms of poisoning are not severe, DuoDote™ Auto-Injector 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.

PLEASE CLICK [HERE](#) TO VIEW FULL PRESCRIBING INFORMATION.

[http://www.meridianmeds.com/pdf/Duodote_Pack_Insert.pdf]

or click [here](#) to launch accompanying Acrobat PDF document



For More Information

- To request additional educational materials, or to order DuoDoteTM, please contact Meridian Medical Technologies
 - Via toll free call at 1-800-638-8093
 - Via e-mail at customerservice@meridianmt.com
 - On the Web at www.DuoDote.com



DuoDote Auto-Injector, the DuoDote Logo, Mark I Kit, and BinaJect are trademarks of Meridian Medical TechnologiesTM, Inc., a wholly owned subsidiary of King Pharmaceuticals[®], Inc.
Copyright © 2009 Meridian Medical TechnologiesTM, Inc., a wholly owned subsidiary of King Pharmaceuticals[®], Inc. All rights reserved.
MMT6152 06/2009

References:

1. DuoDote Auto-Injector [package insert]. Columbia, MD: Meridian Medical Technologies, Inc; 2007. http://www.meridianmeds.com/pdf/Duodote_Pack_Insert.pdf. Accessed September 7, 2007.
2. AtroPen Auto-Injector [package insert]. Columbia, MD: Meridian Medical Technologies, Inc; 2007. http://www.meridianmeds.com/pdf/AtroPen_Pack_Insert.pdf. Accessed September 7, 2007.
3. Pralidoxime Chloride Injection (Auto-Injector) [package insert]. Columbia, MD: Meridian Medical Technologies, Inc; 2007. http://www.meridianmeds.com/pdf/2Pam_Cl_Pack_Insert.pdf. Accessed September 7, 2007.
4. Sidell FR. Nerve agents. In: Sidell FR, Takafuji ET, Franz DR, eds. *Textbook of Military Medicine: Medical Aspects of Chemical and Biological Warfare*. Washington, DC: Office of The Surgeon General at TMM Publications Borden Institute; 1997:129-181.
5. Agency for Toxic Substances and Disease Registry. Medical Management Guidelines (MMGs) for nerve agents: tabun (GA); sarin (GB); soman (GD); and VX. <http://www.atsdr.cdc.gov/MHMI/mmg166.html>. Accessed September 7, 2007.
6. Diazepam Auto-Injector (C-IV) [package insert]. Columbia, MD: Meridian Medical Technologies, Inc; 2007. http://www.meridianmeds.com/pdf/Diazepam_Pack_Insert.pdf. Accessed September 7, 2007.

