June 29, 2015

Dear Health Care Providers,

Dual-chamber auto-injectors containing a sterile solution of atropine (2.1 mg/0.7 mL) and a sterile solution of pralidoxime chloride (600 mg/2 mL) are held in this CHEMPACK container to treat people exposed to life-threatening organophosphorus-containing nerve agents, such as sarin and organophosphorus insecticides.

These auto-injectors are manufactured under two different labels: Antidote Treatment – Nerve Agent Auto-Injector (ATNAA) for military use and DuoDote for civilian use. This container holds ATNAA, which can be used in civilian populations if DuoDote instructions for use are followed. These instructions are provided in this CHEMPACK container.

ATNAA and DuoDote are identical products with different labeling and instructions for use. The U.S. Food and Drug Administration (FDA) is aware that the Centers for Disease Control and Prevention has stocked ATNAA for civilian populations due to current production challenges of the DuoDote auto-injector. Some ATNAA product in this container may have passed its original labeled expiration date; however, FDA has advised that this product is safe and effective for three years beyond the expiration date on the label. While this product can and should be used if needed, it has not been re-labeled to reflect the new use-by date.

You are asked as a health care provider to administer ATNAA to people, as appropriate, based on the DuoDote instructions for use.

Considerations for Health Care Providers:

- DuoDote and ATNAA are identical products manufactured by Meridian Medical Technologies, Inc. Both contain a sterile solution of atropine (2.1 mg/0.7 mL) and a sterile solution of pralidoxime chloride (600 mg/2 mL), which are delivered by a single dual-chamber auto-injector.

- DuoDote is approved by FDA to treat civilians exposed to life-threatening organophosphorus-containing nerve agents, such as sarin and organophosphorus insecticides. ATNAA is approved by FDA to treat the same exposures but is approved for use by military personnel.

- The only differences between DuoDote and ATNAA are the labeling and the instructions for use on the package inserts.

- Health care providers, including emergency medical services, should follow the DuoDote instructions for use when administering ATNAA to civilians. These instructions and this letter are included in every CHEMPACK container that stores ATNAA.

Thank you for your dedication to protecting the health of our population. Questions regarding the ATNAA auto-injector contained in this CHEMPACK should be directed to dsns-request@cdc.gov.

ATNAA Lots[1]

Lot Number	Manufacturer's Original Labeled Expiry Date	New Use Date (up to 3 years beyond manufacturer's original expiry date)
9M1259	March 2013	March 2016
9M1260	March 2013	March 2016
9M1354	March 2013	March 2016
9M1460	May 2013	May 2016
9M1461	May 2013	May 2016
9M1462	May 2013	May 2016
9M1471	May 2013	May 2016
9M1473	May 2013	May 2016
9M1483	May 2013	May 2016
9M1484	May 2013	May 2016
9M1557	June 2013	June 2016
9M1558	June 2013	June 2016
9M1559	June 2013	June 2016
9M1571	June 2013	June 2016
9M1573	June 2013	June 2016
9M1582	July 2013	July 2016
9M1583	July 2013	July 2016
9M1584	July 2013	July 2016
9M1593	July 2013	July 2016
9M1594	July 2013	July 2016
9M1759	September 2013	September 2016
9M1760	September 2013	September 2016
0M1050	December 2013	December 2016
0M1075	December 2013	December 2016
0M1076	December 2013	December 2016
0M1077	December 2013	December 2016
0M1086	January 2014	January 2017
0M1087	January 2014	January 2017
0M1088	January 2014	January 2017
0M1119	January 2014	January 2017
0M1120	January 2014	January 2017
0M1121	January 2014	January 2017
0M1130	January 2014	January 2017
0M1131	January 2014	January 2017

[1] This list updates and replaces the lists of ATNAA lots that were identified as being eligible for use for up to 1 year or 2 years beyond the manufacturer's original expiry date and that were identified, respectively, in FDA's May 23, 2014, and March 17, 2015, memoranda to DoD. Some ATNAA lots included in this table have gone through Shelf-Life Extension Program (SLEP) testing, and it is possible that additional lots listed in this table might go through SLEP testing in the future. Therefore, it is possible that some of the lots listed in this table might now–or might at some point in the future–have new use dates that are beyond the dates included in this table. This updated list includes a minimum extension period of up to three (3) years beyond the manufacturer's original labeled expiry date and does not change any applicable SLEP extensions for DoD ATNAA product. Questions related to the expiration dating of SLEP-tested lots listed in this table should be directed to the DoD SLEP Program Manager.

Lot Number	Manufacturer's Original Labeled Expiry Date	New Use Date (up to 3 years beyond manufacturer's original expiry date)
0M1132	January 2014	January 2017
0M1169	February 2014	February 2017
0M1170	February 2014	February 2017
0M1171	February 2014	February 2017
0M1180	March 2014	March 2017
0M1181	March 2014	March 2017
0M1182	March 2014	March 2017
0M1191	March 2014	March 2017
0M1192	March 2014	March 2017
0M1193	March 2014	March 2017
0M1248	March 2014	March 2017
0M1249	March 2014	March 2017
0M1250	March 2014	March 2017
0M1259	March 2014	March 2017
0M1260	March 2014	March 2017
0M1261	March 2014	March 2017
0M1538	June 2014	June 2017
0M1539	June 2014	June 2017
0M1540	June 2014	June 2017
0M1549	June 2014	June 2017
0M1550	June 2014	June 2017
0M1551	June 2014	June 2017
0M1560	July 2014	July 2017
0M1561	July 2014	July 2017
0M1562	July 2014	July 2017
0M1571	July 2014	July 2017
0M1572	July 2014	July 2017
0M1573	July 2014	July 2017
0M1582	July 2014	July 2017
0M1583	July 2014	July 2017
0M1584	July 2014	July 2017
0M1646	August 2014	August 2017
0M1647	August 2014	August 2017
0M1660	September 2014	September 2017
0M1661	September 2014	September 2017
0M1662	September 2014	September 2017
0M1671	September 2014	September 2017
0M1672	September 2014	September 2017
0M1673	September 2014	September 2017
1M1015	December 2014	December 2017
1M1016	December 2014	December 2017
1M1017	December 2014	December 2017
1M1026	December 2014	December 2017
1M1027	December 2014	December 2017
1M1028	December 2014	December 2017

Lot Number	Manufacturer's Original Labeled Expiry Date	New Use Date (up to 3 years beyond manufacturer's original expiry date)
1M1037	December 2014	December 2017
1M1038	December 2014	December 2017
1M1082	December 2014	December 2017
1M1083	December 2014	December 2017
1M1084	December 2014	December 2017
1M1093	January 2015	January 2018
1M1094	January 2015	January 2018
1M1095	January 2015	January 2018
1M1104	January 2015	January 2018
1M1105	January 2015	January 2018
1M1106	January 2015	January 2018
1M1132	February 2015	February 2018
1M1133	February 2015	February 2018
1M1134	February 2015	February 2018
1M1144	February 2015	February 2018
1M1145	February 2015	February 2018
1M1154	March 2015	March 2018
1M1155	March 2015	March 2018
1M1425	May 2015	May 2018
1M1426	May 2015	May 2018
1M1427	May 2015	May 2018
1M1436	May 2015	May 2018
1M1437	May 2015	May 2018
1M1438	May 2015	May 2018
1M1447	May 2015	May 2018
1M1449	May 2015	May 2018
1M1512	June 2015	June 2018
1M1513	June 2015	June 2018
1M1514	June 2015	June 2018
1M1590	August 2015	August 2018
1M1591	August 2015	August 2018
1M1600	August 2015	August 2018
1M1601	August 2015	August 2018
1M1602	August 2015	August 2018
1M1612	September 2015	September 2018
1M1613	September 2015	September 2018
1M1622	September 2015	September 2018
1M1623	September 2015	September 2018
1M1624	September 2015	September 2018
1M1633	September 2015	September 2018
1M1635	September 2015	September 2018
1M1726	September 2015	September 2018
1M1727	September 2015	September 2018
1M1736	October 2015	October 2018
1M1737	October 2015	October 2018

Lot Number	Manufacturer's Original Labeled Expiry Date	New Use Date (up to 3 years beyond manufacturer's original expiry date)
1M1738	October 2015	October 2018
1M1747	October 2015	October 2018
1M1748	October 2015	October 2018
1M1749	October 2015	October 2018
1M1758	October 2015	October 2018
1M1759	October 2015	October 2018
1M1760	October 2015	October 2018
1M1769	October 2015	October 2018
1M1770	October 2015	October 2018
1M1771	October 2015	October 2018
1M1780	November 2015	November 2018
1M1781	November 2015	November 2018
1M1782	November 2015	November 2018
1M1843	November 2015	November 2018
1M1844	November 2015	November 2018
2M1018	December 2015	December 2018
2M1019	December 2015	December 2018
2M1020	December 2015	December 2018
2M1029	December 2015	December 2018
2M1030	December 2015	December 2018
2M1031	December 2015	December 2018
2M1247	May 2016	May 2019
2M1257	May 2016	May 2019
2M1258	May 2016	May 2019
2M1431	June 2016	June 2019
2M1432	June 2016	June 2019
2M1501	September 2016	September 2019
2M1502	September 2016	September 2019
2M1503	September 2016	September 2019
2M1513	September 2016	September 2019
2M1514	September 2016	September 2019
2M1523	September 2016	September 2019
2M1524	September 2016	September 2019
2M1525	September 2016	September 2019
2M1534	September 2016	September 2019
2M1535	September 2016	September 2019
2M1536	September 2016	September 2019

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.

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.

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.

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.
7) After the drug has been administered, push the needle against a hard surface to bend the needle back against the DuoDote Auto-Injector.
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.

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

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)!

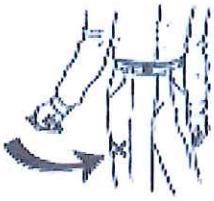
1) Tear open the plastic pouch at any of the notches. Remove the DuoDote Auto-Injector from the pouch.

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.**

Self Aid



Emergency Personnel Aid

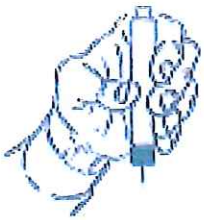
5) Swing and firmly push the Green Tip straight down (a 90° angle) against the mid-outer thigh. Continue to firmly push until you feel the DuoDote Auto-Injector trigger.

Self Aid

Emergency Personnel Aid

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

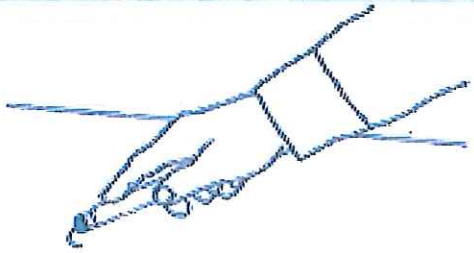
6) Remove the DuoDote Auto-Injector from the thigh and look at Green Tip. If the needle is visible, the drug has been administered. If the needle is not visible, check to be sure the Gray Safety Release has been removed, and then repeat above steps beginning with Step 4, but push harder in Step 5.



Needle visible

Needle not visible

7) After the drug has been administered, push the needle against a hard surface to bend the needle back against the DuoDote Auto-Injector.



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.

DuoDote™ is a trademark of:
Meridian Medical Technologies™, Inc.
Columbia, MD 21046

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