

August 27, 2013

Attention: DuoDote® (atropine and pralidoxime chloride injection) Auto-Injector:
Potential under-dosing or failure to activate

Dear Wholesaler, Healthcare Professional and Emergency Personnel:

Meridian Medical Technologies, a Pfizer Inc. company, would like to inform you that based on a review of product lots at its manufacturing site, Meridian personnel determined that a small number of DuoDote® Auto-Injectors are out of specification. This could potentially prevent some of the units from activating or cause the patient to receive less of the drug than is intended. Delivery of clinically inadequate drug doses is infrequent and occurs in approximately 7 units out of a thousand DuoDote® Auto-Injectors.

DuoDote® Auto-Injector is indicated for the treatment of poisoning by organophosphorous nerve agents as well as organophosphorous insecticides.

Organophosphorus poisoning can result in cardiac arrest, respiratory distress and/or arrest, and seizures. Pralidoxime has its most critical effect in relieving the respiratory muscle paralysis. Inadequate dosing with pralidoxime will delay this effect and if treatment is delayed too long, the reversal of muscle paralysis may no longer occur. Atropine reduces secretions in the mouth and respiratory passages, relieves airway constriction, and may reduce centrally-mediated respiratory paralysis caused by organophosphorus chemicals. Inadequate dosing with atropine will delay resolution of these problems.

In cooperation with the U.S. Food and Drug Administration (FDA) and other government agencies, Meridian currently is investigating the issue, implementing corrective action and developing a product replacement plan.

Recommendations to Health Care Providers

We advise customers to retain the product they currently have and to use it per the enclosed product instructions until additional information about replacement product becomes available. Emergency medical professionals and other trained health care providers should carefully follow the product label. As directed in the label, three units of auto-injectors should be available for use with each patient.

Health care providers are directed to verify the visible presence of the needle following administration and to follow these instructions:

1. After the DuoDote® Auto-Injector triggers, hold it firmly against the injection site for approximately 10 seconds. Remove the DuoDote® Auto-Injector from the thigh and look at the green tip.
 - a. If the needle is is visible, the drug chamber contents will have been administered but in some instances the DuoDote® may not have contained the full intended dose
 - b. If the needle is not visible, check to be sure the gray safety release has been removed, and then repeat the administration instructions.
 - c. If the needle is still not visible, deploy another unit and repeat the injection.
2. Wait 10 to 15 minutes after the first injection. If the patient does not develop severe symptoms, no further injection is required but definitive medical care should be sought immediately.
3. If at any time after the first injection the patient experiences severe symptoms, two additional injections should be administered in rapid succession and definitive medical care should be sought immediately.

As mentioned above, the company is working with the FDA and other government agencies to resolve the situation. Meridian and government agencies are working together to ensure that customers receive replacement product as quickly as possible, and based on priority of need. FDA is actively reviewing data related to DuoDote® performance beyond its labeled expiration date, and will provide additional information and guidance regarding expired product or product nearing its expiration date. Product beyond expiry should be held for the time being until further guidance can be provided by FDA.

Recommendations to wholesalers

It is not recommended that you return the product you currently have. However, it is important that this information be provided to all appropriate dispensing staff. If you further distributed this product to any other accounts, please communicate this information to those accounts immediately.

Reporting

As of the date of this letter there have been no field-related reports of any adverse effects related to this issue.

As with all medical products, healthcare professionals and consumers are strongly encouraged to report any adverse events that are associated with the use of DuoDote® to either Pfizer Safety (1-800-438-1985) or the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or fax:

- Online: www.fda.gov/medwatch/report.htm
- Regular mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm
Mail to address on the pre-addressed form
- Fax: 1-800-FDA-0178

Indication

DuoDote® (atropine and pralidoxime chloride injection) Auto-Injector is indicated for the treatment of poisoning by organophosphorous nerve agents as well as organophosphorous insecticides.

Important Safety Information

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. It is intended as an initial treatment of the symptoms of organophosphorous nerve agent or insecticide poisoning; definitive medical care should be sought immediately.

Individuals should not rely solely upon agents such as atropine and pralidoxime to provide complete protection from organophosphorous nerve agents and insecticide poisoning. Primary protection against exposure to organophosphorous nerve agents and insecticides 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 organophosphorous nerve agent or insecticide poisoning should avoid contaminating themselves by exposure to the victim's clothing.

In the presence of life-threatening poisoning by organophosphorous nerve agents or insecticides there are no absolute contraindications to the use of DuoDote®. 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 compound of the product.

No more than three doses should be administered unless definitive medical care (eg, hospitalization, respiratory support) is available. Elderly people and children may be more susceptible to the effects of atropine. DuoDote® is pregnancy Category C and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Safety and effectiveness in children have not been established.

Muscle tightness and sometimes pain may occur at the injection site. The most common adverse effects of atropine can be attributed to its antimuscarinic action and include dryness of mouth, blurred vision, dry eyes, photophobia, confusion, headache, and dizziness among others. Pralidoxime chloride's adverse effects include changes in vision, dizziness, headache, drowsiness, nausea, tachycardia, increased blood pressure, muscular weakness, dry mouth, emesis, rash, dry skin, hyperventilation, decreased renal function, excitement, manic behavior, and transient elevation of liver enzymes and creatine phosphokinase. When atropine and pralidoxime are used together, the signs of atropinization may occur earlier than might be expected when atropine is used alone.

Please see enclosed full Prescribing Information.

If you require further information about this product, please call 1-866-478-6277.

I thank you for your time and consideration in this matter.

Best Regards,



Tom Handel
SVP-Commercial Pharmaceuticals