

December 4, 2013

Attention: FDA update on AtroPen® (atropine), DuoDote® (atropine and pralidoxime chloride injection), morphine sulfate, pralidoxime chloride and diazepam Auto-Injectors

Dear Wholesaler, Healthcare Professional and Emergency Personnel:

Please see the attached Alert Notice from the U.S. Food and Drug Administration (FDA) regarding a potential extension of expiration dates for AtroPen® (atropine), DuoDote® (atropine and pralidoxime chloride injection), morphine sulfate, pralidoxime chloride and diazepam auto-injectors.

In the Alert Notice, **the FDA advises users to retain the auto-injector products listed above that are nearing or beyond their labeled expiration dates as it reviews data for the potential use of these products beyond the labeled expiration date.**

If you require further information about the attached FDA Alert Notice, please contact Brad Leissa at brad.leissa@fda.hhs.gov or Brooke Courtney at brooke.courtney@fda.hhs.gov.

If you require further information about the auto-injectors mentioned in the FDA Alert Notice, please contact Meridian's customer service office at 1-866-478-6277.

Sincerely,



Tom Handel
SVP-Commercial Pharmaceuticals

Recommendations to wholesalers

If you further distributed any of the above listed products, please communicate this information to those accounts immediately.

FDA alerts health care providers and emergency responders of a potential extension of expiration dates for certain auto-injectors manufactured by Meridian Medical Technologies.

The U.S. Food and Drug Administration is aware of a disruption in supply to health care providers and emergency response personnel of Atropen (atropine), DuoDote (atropine/pralidoxime chloride), morphine sulfate, pralidoxime chloride, and diazepam auto-injectors manufactured by Meridian Medical Technologies, a Pfizer Inc. company. FDA and Meridian are working together to resolve the disruption as quickly as possible, but it is unclear how long this disruption may persist.

As communicated on September 5, 2013, FDA concluded that it was scientifically supported that certain lots of DuoDote can be used for an additional year beyond the manufacturer's original labeled expiration date. FDA is continuing to assess whether these identified lots of DuoDote can receive further expiration date extensions if needed, and whether additional lots of DuoDote that were not listed in FDA's September 5, 2013, memo can have their expiration date extended.

FDA is currently reviewing data for the potential use of Atropen (atropine), DuoDote (atropine/pralidoxime chloride), morphine sulfate, pralidoxime chloride, and diazepam auto-injectors beyond their labeled expiration dates in order to mitigate any potential shortages of these medically necessary drugs. Products nearing or beyond their labeled expiration dates **should be retained** until further guidance is provided by FDA.

What health care providers and emergency response personnel should know:

- Health care providers and emergency response personnel who have any of the auto-injectors manufactured by Meridian identified above that are nearing or beyond the labeled expiration date should retain the products until FDA is able to provide additional information regarding the continued use of these products.
- Due to medical necessity and potential drug shortages, FDA is reviewing data for the potential use of these products beyond their labeled expiration dates.
- FDA will provide additional information about use of these products beyond the labeled expiration date in the coming weeks. Until FDA provides additional information, these expired auto-injectors may be used for patient care under emergency situations when no other product is available.
- Health care providers and emergency response personnel should maintain and monitor these products under the storage conditions described in the product labeling information.
- FDA continues to work with Meridian to resolve manufacturing issues.
- It is unclear at this time when Meridian will have additional inventory of these auto-injectors available.

If health care providers and emergency response personnel have additional questions about these auto-injectors, please contact Meridian's customer service office at 1-866-478-6277.

FDA asks health care providers and consumers to report any adverse events that are associated with the use of any of these products to either Pfizer Safety (1-800-438-1985) or to the [FDA's MedWatch Adverse Event Reporting](#) program by:

- completing and submitting the report online at www.fda.gov/medwatch/report.htm; or
- downloading and completing the [form](#), then submitting it via fax at 1-800-FDA-0178.