

DuoDote® (atropine/pralidoxime) - Expanded indication

- On October 6, 2017, the FDA approved Meridian's <u>DuoDote (atropine/pralidoxime)</u> injection, for the treatment of poisoning by organophosphorus nerve agents as well as organophosphorus insecticides in adults and pediatric patients weighing more than 41 kg (90 pounds).
 - Previously, DuoDote was indicated only in adults.
 - The safety and effectiveness of DuoDote in pediatric patients < 41 kg (90 pounds) have not been established.
- The safety and effectiveness of atropine in DuoDote in patients weighing > 41 kg (90 pounds) is supported by published literature.
 - Adverse events seen in pediatric patients treated with atropine are similar to those that
 occur in adult patients, although central nervous system complaints are often seen earlier
 and at lower doses.
- The safety and effectiveness of pralidoxime chloride in DuoDote in patients > 41 kg (90 pounds) is supported by data from pharmacokinetic studies in adults and experience in the pediatric population.
- The recommended initial dosage of DuoDote for patients experiencing ≥ 2 mild symptoms is one injection intramuscularly (IM) into the mid-lateral thigh. For patients experiencing severe symptoms, three IM injections should be administered into the mid-lateral thigh in rapid succession.
 - The DuoDote autoinjector should be administered by healthcare providers who have had adequate training in the recognition and treatment of nerve agent or insecticide intoxication.
 - Consult the DuoDote drug label for explanation of mild and severe symptoms.



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