



Lomotil® (atropine/diphenoxylate) – Revised indication and new contraindication

- On October 5, 2017, the [FDA approved](#) updates to the *Indications* and *Contraindications* sections of the [Lomotil \(atropine/diphenoxylate\)](#) drug label, to limit use to patients ≥ 13 years of age, and to expand the contraindications for pediatric patients from 2 years old to < 6 years old secondary to the risk of respiratory and central nervous system (CNS) depression.
 - Lomotil is a Schedule V controlled substance (C-V).
- Previously, Lomotil was indicated as adjunctive therapy in the management of diarrhea, and dosing recommendations were provided for pediatric patients as young as 2 years old.
- Cases of severe respiratory depression and coma, leading to permanent brain damage or death have been reported in patients < 6 years of age who received Lomotil. Lomotil is contraindicated in patients < 6 years of age due to these risks.
- In addition, the *Warnings* section was updated to add a description of the anticholinergic and opioid toxicities.
 - Toxicities associated with the atropine and diphenoxylate components of Lomotil have been reported.
 - The initial presenting symptoms may be delayed by up to 30 hours due to prolonged gastric emptying time induced by diphenoxylate hydrochloride.
 - Clinical presentations vary in terms of which toxicity (anticholinergic vs. opioid) will present first or predominate; non-specific findings have been reported and include symptoms such as drowsiness.
- The recommended dose of Lomotil in patients ≥ 13 years of age is two tablets orally four times per day (maximum daily dose of 20 mg/day of diphenoxylate). After initial control has been achieved, the Lomotil dose may be reduced to meet individual requirements. Control may often be maintained with as little as two Lomotil tablets daily.
 - If clinical improvement of chronic diarrhea after treatment with the maximum recommended daily dose is not observed within 10 days, Lomotil should be discontinued as symptoms are unlikely to be controlled by further administration.
- Other updates were made to the following sections:
 - *Adverse Reactions* section to add “hallucinations”.
 - *Contraindications* section to add *Clostridium difficile* as the organism associated with pseudomembranous enterocolitis.
 - *Overdosage* section to include opioid and anticholinergic effects to describe overdose symptoms and update current management of toxicity.



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