Lomotil Tablets
Lomotil Liquid

Presentation

Lomotil Tablets
White tablets engraved "SEARLE" on one side. Each tablet contains Diphenoxylate Hydrochloride B.P. 2.5 milligrams with Atropine Sulphate Ph.Eur. 25 micrograms.

Lomotil Liquid
Red, cherry flavoured liquid. Each 5 ml measure contains Diphenoxylate Hydrochloride B.P. 2.5 milligrams with Atropine Sulphate Ph.Eur. 25 micrograms.

Uses
Adjunctive therapy to appropriate rehydration in diarrhoea
Control of stool formation after colostomy or ileostomy
Relief of symptoms in chronic mild ulcerative colitis (see Warnings)

Dosage and Administration
Caution: The recommended dosage should not be exceeded. Once satisfactory control is achieved, dosage should be reduced to suit the requirements of the individual patient.

Adults
The recommended starting dose is four tablets, or four 5 ml measures, followed by two tablets or two 5 ml measures every six hours.

Elderly
Consideration should be given to the presence of other disease and concomitant drug therapy (see Precautions).

Children
Recommended dosage guide
Under 4 years — not recommended
4-8 years 1 tablet or one 5 ml measure three times daily.
9-12 years 1 tablet or one 5 ml measure four times daily.
13-16 years 2 tablets or two 5 ml measure three times daily.

Contra-indications, Warnings, etc.
Lomotil is contra-indicated in patients with a known hypersensitivity to diphenoxylate hydrochloride or atropine, in patients with jaundice, intestinal obstruction, acute ulcerative colitis, and in the treatment of diarrhoea associated with pseudomembranous enterocolitis.
Appropriate fluid and electrolyte therapy should be given to protect against dehydration. If severe dehydration or electrolyte imbalance is present, Lomotil should be withheld until appropriate corrective therapy has been initiated.
In some patients with ulcerative colitis, agents which inhibit intestinal motility or delay intestinal transit time have been reported to induce toxic megacolon. Patients with ulcerative colitis should be observed carefully and Lomotil therapy should be discontinued promptly if abdominal distension or other untoward symptoms develop.
Lomotil should be used with extreme caution in patients with advanced hepatorenal disease and in all patients with abnormal liver function since hepatic coma may be precipitated.

Precautions
Because a subtherapeutic dose of atropine is added to Lomotil, atropinic effects may occur in susceptible individuals or in overdosage. Individuals with Down's syndrome appear to have an increased susceptibility to the actions of atropine.

Drug Interactions
Since the chemical structure of diphenoxylate hydrochloride resembles that of meperidine hydrochloride, concurrent use with MAO inhibitors could precipitate hypertensive crisis. Close observation is required when these medications are given concomitantly with diphenoxylate hydrochloride.
Diphenoxylate hydrochloride may potentiate the action of central nervous system depressants such as barbiturates, tranquilisers and alcohol.

Pregnancy
Animal teratology and reproduction studies have demonstrated no adverse effects. The safety of Lomotil in pregnancy has not been established. However, as with all drugs, caution is recommended when used in early pregnancy.

Nursing mothers
Diphenoxylate hydrochloride and atropine sulphate may be excreted in human milk. If a nursing mother is taking Lomotil, the infant may exhibit some effect of the drug.

Adverse effects
Adverse reactions reported include:
Central nervous system: malaise/lethargy/sedation/somnolence, confusion, dizziness, restlessness, depression, euphoria, hallucinations, headache.
Allergic: anaphylaxis, angioedema, urticaria, pruritus.
Gastrointestinal system: paralytic ileus, toxic megacolon, gastrointestinal intolerance such as nausea and vomiting, anorexia, abdominal discomfort.
Atropine effects, such as flushing, dryness of the skin and mucous membranes, tachycardia, hyperthermia and urinary retention may occur, especially in children.

Overdosage
Accidental overdosage may produce narcosis with respiratory depression or atropine poisoning or both, particularly in children. Symptoms of overdosage include dryness of the skin and mucous membranes, flushing, hyperthermia and tachycardia, nystagmus, pinpoint pupils, hypotonic reflexes, lethargy, coma and severe respiratory depression. The onset of symptoms of overdosage may be considerably delayed and respiratory depression may not become evident until as late as 12 to 30 hours after ingestion and may recur in spite of initial response to narcotic antagonists.
Continuous observation should be maintained for at least 48 hours.
If respiratory depression develops, naloxone, a specific antidote, should be administered. The duration of action of naloxone hydrochloride is considerably shorter than that of diphenoxylate hydrochloride and repeated injections of the antidote may be required. Establishment of a patent airway and artificial ventilation may be needed. If the patient is not comatose gastric lavage and administration of a slurry of activated charcoal may be indicated.

Pharmaceutical Precautions
Store below 30°C (86°F).

Package Quantities
Lomotil Tablets: Packs of 20 and 100 tablets.

Lomotil Liquid: Bottles containing 60 ml.

Further Information
Nil

SEARLE

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