

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Lomotil tablets (POM)
Dymotil tablets (P)
Co-phenotrope 2.5/0.025 tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2.5mg of diphenoxylate hydrochloride BP and 0.025mg of atropine sulphate Ph.Eur

3 PHARMACEUTICAL FORM

White tablet with “GS10” engraved on one side

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

POM product

Adults and children:

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

P product

Adults only (aged 16 years and over):

Adjunctive therapy to appropriate rehydration in acute diarrhoea

4.2 Posology and method of administration

Route of administration

Oral

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

POM product

Adults:

The recommended starting dosage is four tablets followed by two tablets every six hours.

Elderly:

Consideration should be given to the presence of other diseases and concomitant drug therapy (see precautions)

Children:

Recommended dosage guide:

Under 4 years:- Not recommended

4-8 years:- 1 tablet three times daily

9-12 years:- 1 tablet four times daily

13-16 years:- 2 tablets three times daily

P product

Adults:

The recommended starting dose is four tablets followed by two tablets every six hours. The maximum dose is 10 tablets in the first 24 hours and 8 tablets in 24 hours thereafter. This should not be exceeded.

Elderly:

The dose is as for adults. Consideration should be given to the presence of other disease and concomitant therapy (see precautions).

Children:

Not for use in children under 16 years of age.

4.3 Contraindications

POM product

Lomotil is contraindicated in patients with known hypersensitivity to diphenoxylate hydrochloride or atropine, in patients with jaundice, intestinal obstruction, acute ulcerative colitis, in the treatment of diarrhoea associated with pseudomembranous enterocolitis, and in patients with a raised intracranial pressure, and patients with head injury.

Contraindicated in myasthenia gravis, pyloric stenosis, paralytic ileus and prostatic enlargement.

P product

Dymotil is contraindicated in patients with a known hypersensitivity to diphenoxylate hydrochloride or atropine, in patients with jaundice, intestinal obstruction, any inflammatory bowel disease, including all forms of ulcerative colitis, and in the treatment of diarrhoea associated with pseudomembranous enterocolitis. Dymotil is also contraindicated in patients with Down's syndrome, and in patients with a raised intracranial pressure, and patients with head injury.

Contraindicated in myasthenia gravis, pyloric stenosis, paralytic ileus and prostatic enlargement.

4.4 Special warnings and precautions for use

Appropriate fluid and electrolyte therapy should be given to protect against dehydration. If severe dehydration or electrolyte imbalance is present, the medicine should be withheld until appropriate corrective therapy has been initiated. In some patients with ulcerative colitis, agents which inhibit intestinal mobility 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.

The medicine should be used with extreme caution in patients with advanced hepatorenal disease, and in patients with abnormal liver function, since hepatic coma may be precipitated.

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

Additionally for the P Product

If symptoms persist for more than 24 hours, the patient should consult a doctor. Dymotil is for the symptomatic relief of acute diarrhoea, and is not a substitute for rehydration therapy.

4.5 Interaction with other medicinal products and other forms of interaction

The following interaction have to be considered in the use of Lomotil Tablets:-
Lomotil antagonises the effect of Domperidone, Metoclopramide, Bethanecol/Carbachol, Cisapride, Galantamine, Neostigmine/pyridostigmine, and Pilcarpine.

The antimuscarinic side effects of Lomotil are increased by Amantadine, Antihistamines (sedative and non-sedative), Clozapine, Disopyramide, Fluspiriline, Loxapine, MAOI's, Nefopam, Olanzapine, Phenothiazines, Quantiapine, Remoxipride, Terfenadine, Tricyclic antidepressants, and Zotepine.

Dry mouth prevents the dissolution of sublingual nitrate tablets, such as glyceryl trinitrate.

The effect of Lomotil is antagonised by Dompezil.

The effect of Lomotil is increased by Memantine.

Lomotil may reduce the plasma levels of Levodopa (in combination and sole products).

Lomotil reduces the absorption of Ketoconazole.

4.6 Pregnancy and lactation

POM product

Pregnancy

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

Lactation

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

P product

Pregnancy and Lactation

Dymotil should not be used during pregnancy and in nursing mothers.

4.7 Effects on ability to drive and use machines

Some of the undesirable effects such as sedation, drowsiness or dizziness may affect the ability to drive or operate machines. If affected, patients should be advised not to drive or operate machinery.

4.8 Undesirable effects

The side effects of Lomotil Tablets include malaise, lethargy, sedation, somnolence, confusion, dizziness, restlessness, depression, euphoria, hallucinations, headache, and fever.

Anaphylaxis, angioedema, urticaria and pruritus have been reported side effects.

Gastrointestinal side effects include paralytic ileus, toxic megacolon, nausea, vomiting, abdominal discomfort, constipation and anorexia.

The atropine side effects of Lomotil Tablets include flushing, dryness of the skin and mucous membranes (including dry mouth), cardiac irregularities such as arrhythmias, bradycardia, and palpitations, increased intra-ocular pressure, urinary retention and difficulty in micturition, and respiratory depression in children.

Dilation of pupils with loss of accommodation, photophobia and very rarely angle closure glaucoma can occur.

4.9 Overdose

Accidental overdose may produce narcosis with respiratory depression or atropine poisoning or both, particularly in children. Symptoms of overdose include dryness of the skin and mucous membranes, flushing, hypothermia and tachycardia, nystagmus, pinpoint pupils, hypotonic reflexes, lethargy, coma, and severe respiratory depression. The onset of symptoms of overdose may be considerably delayed and respiratory depression may not become evident until as late as 12-30 hours after ingestion, and may occur 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 patient airway and artificial ventilation may be needed. If the patient is not comatose, gastric lavage and administration of slurry of an activated charcoal may be indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The active ingredient diphenoxylate hydrochloride is a synthetic opioid derivative with selective effects on gastrointestinal smooth muscle. It is essentially devoid of “morphine type subjective effects” at therapeutic doses.

Atropine sulphate is included in the formulation as an anti-abusing agent contributing to the safe use of the product. The dose of atropine sulphate

contained in each tablet is subtherapeutic therefore a pharmaceutical effect due to atropine should not be detected taken at normal therapeutic doses.

5.2 Pharmacokinetic properties

Diphenoxylate hydrochloride is well absorbed from the gastrointestinal tract and extensively metabolised in the liver to diphenoxylic acid (diphenoxin), and hydroxydiphenoxylic acid. It is excreted mainly as metabolites in the urine and bile.

5.3 Preclinical safety data

Diphenoxylate hydrochloride is a well established pharmaceutical active and is the subject of a pharmacopoeial monograph. No specific preclinical studies have therefore been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lomotil/Dymotil tablets contain:

Sucrose

Acacia

Sorbitol

Magnesium stearate

Talc

Light liquid paraffin

6.2 Incompatibilities

None known

6.3 Shelf life

The shelf life of Lomotil/Dymotil tablets is 5 years when stored in blister packs.

6.4 Special precautions for storage

Store in a dry place below 30°C

6.5 Nature and contents of container

POM

Lomotil tablets are supplied in PVC/PVDC/Aluminium foil blister packs of 100, 500, and 1000 tablets.

P

Dymotil tablets are supplied in PVC/PVDC/Aluminium foil blister packs of 20.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Goldshield Pharmaceuticals Ltd
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8 MARKETING AUTHORISATION NUMBER(S)

PL 12762/0040

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/11/1999 / 12/05/2004

10 DATE OF REVISION OF THE TEXT

17 August 2010