

**PRODUCT NAME: LOMOTIL 2.5MG/0.025MG TABLETS.  
PART II**

**SUMMARY OF PRODUCT CHARACTERISTICS**

**1. TRADE NAME OF THE MEDICIANL PRODUCT**

Lomotil 2.5mg/0.025mg Tablets.

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

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

For excipients, see section 6.1

**3. PHARMACEUTICAL FORM**

Tablet

White biconvex tablet with the name "GS10" engraved on one side.

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

Adults only.

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 the suit the requirements of the individual patient.

Adults only:

The recommended starting is four tablets followed by two tablets every six hours until the diarrhea is controlled.

Elderly:

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

Children:

Not recommended.

**4.3 Contraindications**

Lomotil is contraindicated in-patients with a known hypersensitivity to diphenoxylate hydrochloride or atropine, in-patients with jaundice, intestinal obstruction, acute ulcerative colitis, myasthenia gravis, pyloric stenosis and prostatic enlargement and in the treatment of diarrhoea associated with pseudomembranous enterocolitis.

**4.4 Special Warnings and Special Precautions for Use**

Appropriate fluid and electrolyte therapy should be given to protect against dehydration. If severe dehydration or electrolyte is present, Lomotil should be withheld until appropriate corrective therapy has been initiated.

Lomotil should be used in extreme caution in patients with advance hepatorenal disease and in patients with abnormal liver function since hepatic comma may be precipitated.

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

Patients with rare hereditary problems of fructose intolerance, glucose, galactose, malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

**4.5 Interactions with Other Medicaments and Other Forms of Interaction**

Since the chemical structure of diphenoxylate hydrochloride resembles that of meperidine hydrochloride (pethidine), concurrent use with MAO inhibitors could precipitate hypertensive crisis. Close observations is required when these medications are given concomitantly with diphenoxylate hydrochloride.

Diphenoxylate hydrochloride may potentiate the action of narcotic or sedative drugs such as barbiturates, tranquillisers and alcohol.

The anticholinergic effects of this product may be enhanced by the concomitant administration of the other drugs with anticholinergic properties.

**4.6 Pregnancy and Lactation**

Pregnancy

Safety of Lomotil in human pregnancy has not been established, although animal teratology and reproduction studies have demonstrated no adverse effects. Lomotil should not be used in pregnancy unless considered essential by the physician.

Diphenoxylate hydrochloride and atropine sulphate may be excreted in human milk. Lomotil should not be used in nursing mothers.

#### **4.7 Effects on Ability to Drive and Use Machines**

None known.

#### **4.8 Undesirable Effects**

Adverse reactions reported included:

Central nervous:

Malaise/lethargy/sedation/somnolence, confusion, dizziness, restlessness, depression, euphoria, hallucinations, headache and giddiness.

Allergic: anaphylaxis, angioedema, urticaria and pruritus.

Gastrointestinal system: paralytic ileus, toxic megacolon, gastrointestinal intolerance such as nausea and vomiting, anorexia, abdominal discomfort and dry mouth.

Atropine effects such as flushing, dryness of skin and mucous membranes, tachycardia, hypothermia and urinary retention may occur.

Eye disorder: dilation of pupils with loss of accommodation, photophobia, very rarely angle closure glaucoma can occur.

#### **4.9 Overdosage**

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 ingredients 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.

### **5.2 Pharmacokinetic Properties**

Diphenoxylate hydrochloride is well absorbed from the gastrointestinal tract and extensively metabolized in the liver to diphenoxylate acid (difenoxylin) and hydroxydiphenoxylate acid. It is excreted mainly as metabolites in the Urine and bile.

### **5.3 Preclinical Safety Data**

Not applicable.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of Excipients**

Lomotil 2.5mg/0.025mg Tablets contain:

Sucrose  
Acacia  
Sorbitol  
Magnesium stearate  
Talc  
Light liquid paraffin

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf Life**

5 years

### **6.4 Special Precautions for Storage**

Do not store above 30°C  
Store in the original package

### **6.5 Nature and Contents of Container**

Lomotil tablets may be supplied in pvc/foil blister packs of 8,100, 500 and 1000  
Not all pack sizes may be marketed.

### **6.6 Instructions for Use/ Handling**

No special requirement

## **7. MARKETING AUTHORISATION HOLDER**

Goldshiled Pharmaceutical Ltd.  
NLA Tower  
12-16 Addiscombe Rd

**Lomotil 2.5mg/0.025mg Tablets**

**PA 899/7/1**

Croydon  
Surrey  
CR0 0XI  
United Kingdom

**8. MARKETING AUTHORISATION NUMBER**

PA 899/7/1

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION**

24th May 1980/24th June 2005

**10. DATE OF (PARTIAL) REVISION OF THE TEXT**

13/05/2010