



MercuryPharma

# PACKAGE LEAFLET: INFORMATION FOR THE USER

## LOMOTIL® 2.5mg/0.025mg Tablets

### Diphenoxylate Hydrochloride / Atropine Sulphate



#### Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The product is known by the name above but will be referred to as Lomotil Tablets throughout the rest of this leaflet.

#### In this leaflet:

1. What Lomotil Tablets are and what they are used for
2. Before you take Lomotil Tablets
3. How to take Lomotil Tablets
4. Possible side effects
5. How to store Lomotil Tablets
6. Further information

### 1. WHAT LOMOTIL TABLETS ARE AND WHAT THEY ARE USED FOR

Lomotil Tablets contain diphenoxylate hydrochloride and atropine sulphate, which are the active ingredients.

Diphenoxylate has the effect of slowing down the activity of the intestines.

Lomotil is used in the treatment of acute diarrhoea.

When you have diarrhoea, your body loses water and important salts. As well as giving you Lomotil, the doctor may give you medicine to help replace the water and salts that you have lost. In some cases the doctor will not give you Lomotil until after the water and salts have been replaced. The diphenoxylate in Lomotil helps stop diarrhoea by slowing down the movement of the muscles in your intestines.

Atropine relieves the sharp pains you sometimes get with diarrhoea.

### 2. BEFORE YOU TAKE LOMOTIL TABLETS

#### Do not take Lomotil Tablets if:

- you are allergic (hypersensitive) to diphenoxylate, atropine or any of the other ingredients of Lomotil Tablets (see section 6 of this leaflet)
- you have jaundice (yellowing of the whites of the eyes or your skin)
- you have an obstruction of the bowels which prevents food from moving through your digestive system
- you have severe sudden inflammations of the bowels known as acute ulcerative colitis
- you have muscle weakness (myasthenia gravis)
- you have an obstruction of the bowels which prevents food from moving through your digestive system
- you have an enlarged prostate
- you have diarrhoea resulting from a severe disease of the bowels called pseudomembranous enterocolitis. This disease may be caused by certain antibiotics
- you have a head injury or have been told that the pressure inside your head is high.

#### Take special care with Lomotil Tablets

Tell your doctor before you take this medicine if:

- you suffer from kidney or liver disease
- ulcerative colitis and develop a bloated stomach or any side effect (see section 4-Side Effects)
- you have inflammation of the intestines that sometimes occurs following antibiotic treatment
- you have loose stools due to bacterial infection
- you have Down's syndrome as you may be extra-sensitive to Lomotil. You or your carer should discuss this with your doctor before starting treatment.

#### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The effects of Lomotil or these medicines may change, especially if you are taking:

- Medicines for depression known as monoamine oxidase inhibitors (MAOIs), e.g. phenelzine, isocarboxazid, or tricyclic antidepressants, e.g. amitriptyline, clomipramine.
- Medicines for vomiting and feeling sick, e.g. domperidone, metoclopramide .
- Medicines to treat Alzheimer's disease (a disease which causes loss of recent memory) e.g. galantamine, donepezil and memantine
- Medicines which increase muscle contraction, e.g. neostigmine/pyridostigmine, bethanecol.
- Pilocarpine, used to treat glaucoma (increased pressure in the eyes)
- Amantadine and levodopa (used to treat Parkinson's disease)
- Sedative and non-sedative antihistamines (used to treat allergies), e.g. chlorphenamine, cetirizine, terfenadine
- Medicines used to treat serious mental disorders, e.g. clozapine, olanzapine, phenothiazines, quetiapine, zotepine, fluspirilene, loxapine, remoxipride
- Disopyramide (a drug used to control abnormal heart beats)
- Nefopam (a pain killer)
- Glyceryl trinitrate (a medicine given under the tongue for angina chest pain)
- Ketoconazole (a drug used to treat fungal infections)
- Cisapride (used to treat constipation and gastroesophageal reflux disease).

Speak to your doctor if you are unsure about anything before you take this medicine.

#### Taking Lomotil Tablets with food and drink

Be careful if you drink alcohol while you are taking Lomotil, it may affect you more than usual.

#### Pregnancy and breast feeding

Tell your doctor before you are given this medicine if you are or think you may be pregnant or are planning to become pregnant or are breast feeding. Lomotil should not be used in pregnancy unless considered essential by your doctor. You should not take Lomotil if you are breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.



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Version No: **100265/LF/077/04**  
 Product Name: **Lomotil 2.5mg/0.025mg Tablets**  
 Pack Size: 100 Tablets  
 Component: Leaflet  
 SKU: 100265  
 Market: Ireland  
 Production Site: Lomapharm  
 Revision No.: 2  
 Revision Date: 05/03/2015  
 Revised by: ADD

Dimension: 180 x 270 mm  
 Commodity No.: LP1115/01  
 Pharma Code: 218  
 Core Spec Ref: N/A  
 DCMF: N/A  
 Print Colours: Black

Non-Print Colours: **Cutter**

Tech App. Date: 10/03/2015  
 Min. Font Size: 8.5 pt

CRF: **AMCo.CRF.392.2014**  
 DOA: N/A  
 DOI: N/A

### REGULATORY AUTHORITY APPROVAL CONFIRMATION

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**Accept Artwork / Reject Artwork**  
(Please strike off whichever NOT applicable)

Signature .....

Name .....

Date .....





Version No: **100265/LF/077/04**  
 Product Name: **Lomotil 2.5mg/0.025mg Tablets**  
 Pack Size: 100 Tablets  
 Component: Leaflet  
 SKU: 100265  
 Market: Ireland  
 Production Site: Lomapharm  
 Revision No.: 2  
 Revision Date: 05/03/2015  
 Revised by: ADD

Dimension: 180 x 270 mm  
 Commodity No.: LP1115/01  
 Pharma Code: 218  
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### Driving and using machines

Lomotil Tablets may make you feel drowsy or dizzy or affect your concentration. You should not drive or use machines when you first start to take this medicine until you are certain that you are not getting these side effects. If in any doubt, speak to your doctor before you drive or use machines.

### Important information about some of the ingredients of Lomotil Tablets

This medicine also contains sucrose and sorbitol (which are sugars): if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3. HOW TO TAKE LOMOTIL TABLETS

This medicine is not recommended in children.

Always take Lomotil Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Swallow the tablets with a glass of water.

#### Usual Dose

Start by taking four tablets. Six hours later, take two more tablets. After that, take two tablets every six hours until the diarrhoea is controlled.

#### If you take more Lomotil Tablets than you should

If you think that you, or any other person, have taken too many tablets, contact your doctor or hospital casualty department immediately. Take any remaining tablets and this leaflet with you so that the medical staff know exactly what you have taken.

#### If you forget to take Lomotil Tablets

If you miss a dose, wait until your next dose. Do not take the dose you have missed. You can then carry on as before. Do not take more than one dose at a time.

### 4. POSSIBLE SIDE EFFECTS

Like all medicines Lomotil Tablets can cause side-effects, although not everybody gets them.

**All medicines can cause allergic reactions, although serious reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.**

#### The following side effects may occur:

- Feeling generally unwell
- Restlessness
- Depression
- Headache
- Feeling bloated, being or feeling sick, reduced appetite, constipation
- Fast, slow or irregular heartbeat
- Difficulty passing urine
- Tiredness, confusion, dizziness, giddiness
- Drowsiness
- feeling overexcited
- Imagining sensation (hallucination)
- Flushing and dryness of your skin, mouth, throat and nose
- Feeling unusually cold with a high temperature
- Increased pressure in the eye causing changes to vision, dilation of the pupils of the eye, increased sensitivity to light.

Sometimes you can suffer from a condition called 'paralytic ileus'. In this condition the bowels become paralysed and stop working.

If you have ulcerative colitis, you may develop a condition called 'toxic megacolon' while you are taking Lomotil. The symptoms of this are feeling bloated, pain in your stomach, feeling feverish and feeling or being sick. Tell your doctor if you have ulcerative colitis and have any of these symptoms while you are taking Lomotil. Children may experience shortness of breath or have trouble breathing, which could be severe.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

### 5. HOW TO STORE LOMOTIL TABLETS

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original packaging.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

### 6. FURTHER INFORMATION

#### What Lomotil Tablets contains

The active substances are diphenoxylate hydrochloride and atropine sulphate.

The other ingredients are sucrose, acacia, sorbitol (E420), magnesium stearate, talc and liquid paraffin.

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

#### What Lomotil Tablets looks like and contents of pack

Lomotil Tablets are white tablets with GS10 engraved on one side.

They are packed in blister strips and supplied in boxes of 8, 100, 500 or 1000 tablets. Not all pack sizes may be marketed.

#### Marketing authorisation holder

Mercury Pharmaceuticals Ltd., Capital House, 85 King William Street, London EC4N 7BL, UK

#### Manufacturer

Lomapharm, Rudolf Lohmann GmbH KG, Langes Feld 5, 31860 Emmerthal, Germany

This leaflet was last revised in March 2015.

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