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.

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 contains diphenoxylate hydrochloride and atropine sulphate. Diphenoxylate is the active ingredient of Lomotil. It 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. Consequently, your doctor may also give you other medicines 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.

Your doctor may also give you Lomotil to:
• Relieve the pain and diarrhoea associated with mild or long term inflammation of the bowels known as chronic ulcerative colitis
• Reduce the number of stools and make them less watery if you have had a colostomy or ileostomy (part of your bowel removed causing you to use an external bag).

2. Before you take Lomotil Tablets

DO NOT take Lomotil Tablets if:
• You know that you are allergic to diphenoxylate hydrochloride and atropine sulphate or any of the other ingredients of Lomotil (see section 6 of this leaflet).
• You have jaundice (yellowing of your skin or the whites of your eyes caused by liver disease).
• You have an obstruction of the bowels which prevents food from moving through your digestive system.
• You have severe sudden inflammation of the bowels known as acute ulcerative colitis.
• 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.
• You have myasthenia gravis (muscle weakness)
• You have narrowing of the stomach
• You have enlargement of the prostate gland

Take special care with Lomotil Tablets and speak to your doctor if you have:
• kidney or liver disease;
• ulcerative colitis and develop a bloated stomach or any side effect (see section 4 – Side Effects)
• 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 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, betahanecl.
• 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.
• Pilocarpine, used to treat glaucoma (increased pressure in the eyes)
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Pregnancy and breast feeding
Lomotil should not be used during pregnancy or breast feeding. Ask your doctor or pharmacist for advice before taking any medicine.

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
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 DOSES
Adults:
Start by taking four tablets. Six hours later, take two more tablets. After that, take two tablets every six hours.

Children:
Under 4 years - do not use
4 to 8 years – 1 tablet three times a day
9 to 12 years – 1 tablet four times a day
13 to 16 years – 2 tablets three times a day

Space the doses as evenly as possible through the day.

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. Taking too many tablets can be very serious, and may cause unconsciousness or difficulty breathing.

If you forget to take your 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 can sometimes cause side effects, although not everybody gets them.

All medicines can cause allergic reactions although serious allergic 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
- Tiredness, confusion, dizziness
- Redness
- Drowsiness
- Depression
- Feeling overexcited
- Headaches
- Imagining sensations (hallucinations)
- Feeling bloated, being or feeling sick, reduced appetite, constipation

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

5. How to store Lomotil Tablets
Keep this medicine out of the sight and reach of children.
Do not use Lomotil 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 package.

6. Further information
The active substance in Lomotil tablets is diphenoxylate hydrochloride.
Lomotil tablets also contains atropine sulphate, sucrose, asacia, sorbitol (E420), magnesium stearate, talc and liquid paraffin.

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

What Lomotil Tablets look like and contents of the pack
Lomotil Tablets look like and contents of the pack
Lomotil tablets are round, white tablets with GS10 engraved on one side. They are packed in blister strips and supplied in boxes of 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
Lonapharm, Rudolf Lohmann GmbH KG, Langes Feld 5, 31860 Emmerthal, Germany

This leaflet was last revised in December 2013.

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PATIENT INFORMATION LEAFLET
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 become 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.

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1. What Lomotil Tablets are and what they are used for

Lomotil contains diphenoxylate hydrochloride and atropine sulphate. Diphenoxylate is the active ingredient of Lomotil. It has the effect of slowing down the activity of the intestines.

Lomotil is used in the treatment of acute diarrhoea.

When you have diarrhea, your body loses water and important salts. Consequently, your doctor may also give you other medicines 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.

Your doctor may also give you Lomotil to:
• Relieve the pain and diarrhoea associated with mild or long term inflammation of the bowels known as chronic ulcerative colitis
• Reduce the number of stools and make them less watery if you have had a colostomy or ileostomy (part of your bowel removed causing you to use an external bag).

2. Before you take Lomotil Tablets

DO NOT take Lomotil Tablets if:
• You know that you are allergic to diphenoxylate hydrochloride and atropine sulphate or any of the other ingredients of Lomotil (see section 6 of this leaflet).
• You have jaundice (yellowing of your skin or the whites of your eyes caused by liver disease).
• You have an obstruction of the bowels which prevents food from moving through your digestive system.
• You have severe sudden inflammation of the bowels known as acute ulcerative colitis.
• 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
• You have myasthenia gravis (muscle weakness)
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Take special care with Lomotil Tablets and speak to your doctor if you have:
• kidney or liver disease;
• ulcerative colitis and develop a bloated stomach or any side effect (see section 4 - Side Effects)
• Down’s syndrome as you may be extra-sensitive to Lomotil. You or your carer should discuss this with your doctor before starting treatment.

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Please tell your doctor or pharmacist if you are taking or have taken recently 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.
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• 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, risperidone, olanzapine, remirparide
• Disopyramide (a drug used to control abnormal heart beats)
• Nitropil (a pain killer)
• Glyceryl trinitrate (a medicine given under the tongue for angina chest pain)
• Ketoconazole (a drug used to treat fungal infections)
• Clonazepam (used to treat constipation and gastroesophageal reflux disease)

Pregnancy and breast feeding

Lomotil should not be used during pregnancy or breast feeding. Ask your doctor or pharmacist for advice before taking any medicine.

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.

3. How to take Lomotil Tablets

4. Possible side effects

5. How to store Lomotil Tablets

6. Further information
3. How to take Lomotil Tablets

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 DOSES**

**Adults:**

Start by taking four tablets. Six hours later, take two more tablets. After that, take two tablets every six hours.

**Children:**

- Under 4 years – do not use
- 4 to 8 years – 1 tablet three times a day
- 9 to 12 years – 1 tablet four times a day
- 13 to 16 years – 2 tablets three times a day

Space the doses as evenly as possible through the day.

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.

Taking too many tablets can be very serious, and may cause unconsciousness or difficulty breathing.

If you forget to take your 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.

**3. How to take Lomotil Tablets**

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The following side effects may occur:

- Feeling generally unwell
- Tiredness, confusion, dizziness
- Restlessness
- Drowsiness
- Depression
- Feeling overexcited
- Headaches
- Imagining sensations (hallucinations)
- Feeling bloated, being or feeling sick, reduced appetite, constipation
- Flushing and dryness of your skin, mouth, throat and nose
- Fast, slow or irregular heart beat
- Feeling unusually warm with a high temperature
- Difficulty passing urine
- Increased pressure in the eye causing changes to vision
- Sensitivity towards bright light
- Eye disorders
- Giddiness

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

5. How to store Lomotil Tablets

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

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**Manufacturer**

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