

LOMOTIL®

Diphenoxylate hydrochloride and atropine sulfate tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LOMOTIL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you taking LOMOTIL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What LOMOTIL is used for

LOMOTIL used along with other measures for the treatment of acute or chronic diarrhoea.

LOMOTIL contains the active ingredients diphenoxylate hydrochloride and atropine sulfate along with other ingredients. Diphenoxylate reduces diarrhoea by slowing down the movements of the intestines. Because diphenoxylate may be abused by taking it in doses that are larger than prescribed, a small amount of atropine sulfate is included in LOMOTIL. This causes unpleasant effects if larger than normal doses are taken and discourages abuse.

LOMOTIL, in pack sizes of 20 and 100 tablets, is only available with a doctor's prescription. LOMOTIL in a pack size of 8 tablets is available as a pharmacist only medicine.

Before you take LOMOTIL

When you must not use it

Do not take LOMOTIL if:

- **You are allergic to diphenoxylate or atropine or any of the tablet ingredients listed at the end of this leaflet**

If you have an allergic reaction you may get a skin rash, difficulty in breathing, hayfever or faintness.

- **You have jaundice**
- **You have diarrhoea caused by pseudomembranous enterocolitis**

This is a potentially serious infection of the gut, which may occur during or up to several weeks following antibiotic treatment.

- **You have an inflammatory bowel disease such as ulcerative colitis or Crohn's disease**
- **You have bacterial colitis or amoebic colitis.**
- **You are breastfeeding.**

You should use an alternative form of infant feeding while you are taking LOMOTIL

LOMOTIL passes into breast milk, so if you take LOMOTIL while breastfeeding, your baby may have some effects from it.

LOMOTIL is not recommended for children less than 12 years old.

Children, especially very young children, are very sensitive to the effects of LOMOTIL.

LOMOTIL must be kept out of the reach of children, since accidental overdose in children may result in serious breathing difficulties, or even death.

- **Do not use tablets after the use by date, which appears on the label after the letters "EXP".**

They may have no effects at all, or an entirely unexpected effect if you use them after the expiry date.

- **Do not use LOMOTIL if the packaging is torn or shows signs of tampering.**
- **Do not use LOMOTIL to treat any other complaints unless your doctor says to.**
- **Do not give this medicine to anyone else, even if their symptoms seem similar to yours.**

Before you start to use LOMOTIL

Tell your doctor if:

- **You are allergic to any other medicines, or foods, dyes or preservatives**
- **You have any other medical conditions, especially:**
 - Liver disease, jaundice
 - Kidney disease
 - Colitis
 - Down's syndrome
 - History of drug abuse
- **You are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some of the medicines in common use that may interfere with LOMOTIL include:

- Tranquillisers - medicines used to produce calmness, treat anxiety or help you sleep
- Antidepressants - medicines used to treat depression, such as monoamine oxidase inhibitors (MAOI)
- Barbiturates - medicines used to treat epilepsy and to help you sleep.

These medicines may be affected by LOMOTIL or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has a more complete list of medicines to avoid while taking LOMOTIL.

Do not drink alcohol while taking LOMOTIL.

Tell your doctor if you become pregnant while you are taking LOMOTIL.

You should not take LOMOTIL near or at the time of giving birth, because diphenoxylate is chemically related to medicines which can slow down the breathing of newborn infants.

How to take LOMOTIL

Follow your doctor's or pharmacist's instructions on how much LOMOTIL to take and for how long to take it.

The usual starting dose of LOMOTIL is 2 tablets, three or four times a day, until the diarrhoea is under control.

The dose is then usually reduced, so that you are taking just enough tablets to control the diarrhoea. This may be as few as 2 tablets a day.

The usual maximum dose is 8 tablets in a day (24 hours).

Your doctor may want you to stop taking LOMOTIL when your bowel movements return to normal.

If your diarrhoea contains blood or lasts for more than 2 days, tell your doctor.

If you take too much (overdose)

Immediately telephone your doctor, pharmacist or Poisons Information Centre (telephone number: 131126) for advice, or go to Casualty at your nearest hospital, if you think that you or anyone else may have taken a large number of LOMOTIL tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you think someone has taken an overdose of LOMOTIL, or if a child has accidentally taken LOMOTIL tablets, you should get medical help immediately.

Signs that may indicate an overdose are: at first, dryness of the skin and mouth, widening of the pupils of the eye, restlessness, flushing, high temperatures and rapid heartbeat, followed by lack of energy or coma, poor reflexes, constant movements of the eyeballs, pinpoint (small) pupils and slow, shallow breathing (respiratory depression). Sometimes respiratory depression may not occur straight away and may develop as late as 30 hours after an overdose. Patients should be watched for at least 48 hours, preferably in hospital.

While you are using LOMOTIL

Things you must do

Use LOMOTIL exactly as your doctor has prescribed.

Tell all doctors, dentists and pharmacists who are treating you that you are taking LOMOTIL.

Drink plenty of liquids, such as an oral rehydration solution.

Drinking plenty of liquids makes sure you do not become dehydrated (lose too much liquid from your body). If you have become very dehydrated, see your doctor to make sure this is corrected, before taking LOMOTIL.

Eat as little as possible for the first few days.

Eat only plain, bland foods, such as un buttered toast, plain biscuits, boiled potatoes, rice or pasta. Gradually return to your normal diet when the diarrhoea has stopped.

Be careful driving or operating machinery until you know how LOMOTIL affects you.

LOMOTIL can make some people drowsy or dizzy. Make sure you know how you react to LOMOTIL before you drive a car or operate machinery.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using LOMOTIL.

LOMOTIL helps most people with diarrhoea, but it may have unwanted effects in a few people.

All medicines have side effects.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor if you experience any unusual side effects or any changes in your health, while you are taking LOMOTIL.

Side effects which have been reported in patients taking LOMOTIL are:

- Lack of energy
- Confusion
- Drowsiness
- Dizziness
- Restlessness
- Depression
- Euphoria
- Numbness in hands and feet
- Headache
- Allergic wheals and swelling
- Rash
- Swelling of gums
- Itching
- Vomiting
- Nausea
- Loss of appetite
- Abdominal discomfort
- Severe allergic reaction (anaphylaxis)
- Obstruction or paralysis of the intestine

Reported side effects of atropine sulfate are:

- Unusually high fever
- Rapid heartbeat
- Being unable to urinate
- Flushing
- Dry skin and
- Dry mouth.

Tell your doctor if any side effects do not settle down during treatment or are a problem for you, or if you develop any new medical problem while you are taking LOMOTIL.

Ask your doctor or pharmacist about any questions you may have.

After using LOMOTIL

Storage

Keep it where young children cannot reach it, since overdose is especially dangerous in children.

Do not leave it in the car on hot days.

Keep your tablets in their blister pack until it is time to take them.

Store below 30 °C.

Store away from heat, direct light and steamy or damp places. Heat or moisture may cause LOMOTIL tablets to deteriorate.

Disposal

Carefully dispose of any tablets that are no longer needed or are past the expiry date ("EXP"). Ask your pharmacist for advice on disposal of medicines.

Product description

What it looks like

LOMOTIL tablets are white to off-white, uncoated, biconvex tablets marked LT on one side in blister packs of 8, 20 and 100 tablets

Ingredients

LOMOTIL contains 2.5mg diphenoxylate hydrochloride and 25 micrograms atropine sulfate as the active ingredients.

Other ingredients in each tablet are:

Sucrose, acacia, sorbitol, talc, magnesium stearate, liquid paraffin.

Distributor

LOMOTIL is distributed by:

iNova Pharmaceuticals (Australia) Pty Limited

ABN: 13 617 871 539

Level 10, 12 Help Street

Chatswood NSW 2067

Tel (Australia): 1800 630 056

® = Registered Trademark

AUST R 74475

This leaflet was prepared May 2020