

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

LOMOTIL
Diphenoxylate hydrochloride and atropine sulfate tablets USP

Read this carefully before you start taking **LOMOTIL** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LOMOTIL**.

What is LOMOTIL used for?

- LOMOTIL is used along with other medicines to treat diarrhea.

How does LOMOTIL work?

- LOMOTIL reduces the movement of the muscles in your bowel. This slows down the movement of feces in your bowels.

What are the ingredients in LOMOTIL?

Medicinal ingredients: diphenoxylate hydrochloride and atropine sulfate.

Non-medicinal ingredients: acacia, corn starch, mineral oil, magnesium stearate, sorbitol, sucrose and talc.

LOMOTIL comes in the following dosage form:

As tablets containing 2.5 mg diphenoxylate hydrochloride and 0.025 mg atropine sulfate.

Do not use LOMOTIL if you:

- Are allergic to diphenoxylate hydrochloride or atropine sulfate.
- Are allergic to any of the other ingredients in LOMOTIL.
- Have jaundice which is a condition where your skin and the whites of your eyes are yellow.
- Have diarrhea caused by bacteria.

LOMOTIL is not recommended for children under the age of four.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LOMOTIL. Talk about any health conditions or problems you may have, including if you:

- Have a history of dependence or addiction to alcohol, medicines or drugs.
- Are pregnant or planning to become pregnant.
- Are breastfeeding or planning to breastfeed.
- Are severely dehydrated or have an electrolyte imbalance.
- Have or have had liver problems.
- Have or have had a bowel disease called ulcerative colitis.

Other warnings you should know about:

Driving and using machines:

- LOMOTIL may cause drowsiness or dizziness. You should not drive or operate dangerous machinery when you first start to take this medicine.

Use in children:

- LOMOTIL is not recommended for children under the age of four. If your child's doctor has prescribed LOMOTIL they will monitor your child closely. Doctors must be very cautious when giving LOMOTIL to a child especially if the child has Down's syndrome. Talk to your doctor about the safe use of this product by your child.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with LOMOTIL:

- Medicines that may affect your nervous system such as:
 - Barbiturates like phenobarbital,
 - Benzodiazepines (medicines to help you sleep or reduce anxiety like lorazepam, alprazolam),
 - Sedatives (medicines to help you sleep),
 - Anxiolytics (medicines to help reduce anxiety),
 - Tranquilizers (medicines to help calm you down),
 - Muscle relaxants (medicines to help muscle spasms and back pain like methocarbamol, cyclobenzaprine),
 - General anesthetics (medicines used during surgery),
 - Antipsychotics (medicines used to treat schizophrenia or other psychiatric illness like olanzapine, clozapine, haloperidol),
 - Opioids (medicines used to treat pain like oxycodone, codeine, morphine, hydromorphone, meperidine, tramadol),
 - Alcohol,
 - Monoamine oxidase inhibitors, like phenelzine sulphate, tranylcypromine sulphate, moclobemide or selegiline, used to treat depression or Parkinson disease.

How to take LOMOTIL:

- Always take LOMOTIL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- Swallow tablet whole with a glass of water.
- You should drink plenty of water while taking LOMOTIL.

Usual adult dose:

- The usual first dose is 2 tablets 3 or 4 times a day.
- Your doctor will decide how much LOMOTIL you should take after that and for how long you should take it.

Usual dose in children aged 4 and older:

- Your doctor will decide how much your child will receive. The dose they receive will be based on how much they weigh.

Overdose:

If you think you have taken too much **LOMOTIL**, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using LOMOTIL?

These are not all the possible side effects you may feel when taking LOMOTIL. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Feeling ill
- Drowsiness
- Feeling tired
- Restlessness
- Dizziness
- Difficulty sleeping or sleepiness
- Headache
- Blurry vision
- Feeling unusually excited
- Confusion
- A feeling of pins and needles in your hands or feet or another body part
- Feeling depressed
- Loss of appetite, abdominal bloating, abdominal cramps, constipation.
- Dry skin
- Difficulty urinating

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN FREQUENCY			
Respiratory depression (inadequate breathing): difficult or slow breathing.			√
Nervous System Effects: Depression, dizziness or drowsiness, sedation.		√	
Coma			√

Toxic megacolon (swelling of the colon): bloating of the abdomen, bloody or heavy diarrhea, fast heart rate, fever, painful bowel movements, shock, stomach pain, tenderness of the abdomen.			√
Pancreatitis (swelling of the pancreas): fast heart rate, fever, nausea, tenderness when touching the abdomen, upper abdominal pain, vomiting.		√	
Allergic reaction: difficulty breathing, difficulty swallowing, fever, hives, itchy skin, rash, swelling of your tongue, throat or face.			√
Hallucinations: seeing or hearing things that aren't there.		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

Store between 15-25°C and protect from light.

Keep out of reach and sight of children.

If you want more information about LOMOTIL:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website (<http://www.pfizer.ca>), or by calling 1-

800-463-6001.

This leaflet was prepared by Pfizer Canada ULC.

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