

DIASTOP

Diphenoxylate hydrochloride 2.5 mg and Atropine sulphate 0.025 mg Tablets



What is in this leaflet

This leaflet answers some common questions about DIASTOP.

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 DIASTOP 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 DIASTOP is used for

DIASTOP tablets contain a combination of the active ingredients diphenoxylate hydrochloride and atropine sulphate. Diphenoxylate has the effect of slowing down the activity in the intestines.

DIASTOP is used for the treatment of acute and chronic diarrhoea, when proper rehydration is available.

It is also used to relieve the pain and diarrhoea associated with inflammation of the bowels known as ulcerative colitis.

DIASTOP can also be used to reduce the number of stools and make them less watery if you have a colostomy or ileostomy (part of your bowel removed causing you to use an external bag).

This medication has the potential to be abused if it is taken in larger doses than recommended; therefore a very small quantity of atropine sulphate has been included in DIASTOP tablets. The presence of atropine means that if too much DIASTOP is taken, an unpleasant feeling results and therefore discourages abuse.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only from your pharmacy.

Before you take DIASTOP

When you must not take it:

Do not take DIASTOP if you have an allergy to:

- Any medicine containing diphenoxylate hydrochloride or atropine sulphate
- Any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take DIASTOP if:

- 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 diarrhoea caused by pseudomembranous enterocolitis (a potentially serious infection of the gut) which may occur during or after antibiotic treatment
- You have severe sudden inflammation of the bowels such as acute ulcerative colitis or Crohn's disease)
- You have a head injury or have been told that the pressure inside your head is high.
- You have Down's syndrome, as you may be extra sensitive to DIASTOP.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in DIASTOP passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to a child under the age of 2 years.

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

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- Kidney or liver disease
- Ulcerative colitis and develop a bloated stomach

If you have not told your doctor about any of the above, tell him/her before you start taking DIASTOP.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and DIASTOP may interfere with each other. These include:

- Medicines used to treat depression known as monoamine oxidase inhibitors (MAOIs), such as phenelzine, or tricyclic antidepressants such as amitriptyline, clomipramine.
- Medicines used to prevent vomiting and feeling sick, such as domperidone, metoclopramide.
- Medicines used to treat Alzheimer's disease, such as galantamine, donepezil, memantine.
- Medicines which increase muscle contraction, such as neostigmine/pyridostigmine, bethanecol.
- Pilocarpine, used to treat glaucoma (increased pressure in the eyes).
- Amantadine and levodopa (used to treat Parkinson's disease)
- Antihistamines used to treat allergies, such as chlorpheniramine, cetirizine, loratadine.
- Medicines used to treat serious mental disorders, such as clozapine, olanzapine, phenothiazines, quetiapine, zotepine.

- Disopyramide (used to control abnormal heart beats)
- Nefopam (a pain killer)
- Glycerol trinitrate when taken as tablets under the tongue for angina chest pain, as dry mouth prevents the tablets from dissolving
- Ketoconazole (used to treat fungal infections).

These medicines may be affected by DIASTOP or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take DIASTOP

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Adults

The usual starting dose is 2 tablets taken three to four times daily. In acute diarrhoea an initial dose of 4 tablets may be given, followed by 2 tablets every six to eight hours.

After initial control is achieved, reduce the number of tablets so that you are taking just enough tablets to control the diarrhoea.

The usual maximum dose is 8 tablets in a day (24 hours). Do not exceed this dose.

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

Children

Under 2 years – Do not use.
2 to 5 years (15–20 kg) – 1 tablet

twice daily;
5 to 8 years (20–27 kg) – 1 tablet three times daily;
8 to 12 years (27–36 kg) – 1 tablet four times daily;
12 years and over – as for Adults.

Gradually reduce the number of tablets until the diarrhoea is under control.

Do not exceed the recommended dose.

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

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Space the doses as evenly as possible through the day.

If you forget to take it

If you miss a dose, wait until your next dose. Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much DIASTOP. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include

- Flushing and dryness of your skin, mouth, throat and nose

- Feeling unusually warm with a high temperature
- Fast heart rate
- Rapid, uncontrollable movements of the eyes, or pinpoint pupils
- A feeling of tiredness, drowsiness, or lack of energy, low muscle strength
- Difficulty in breathing, coma.

While you are using DIASTOP

Things you must do

Drink plenty of liquids to make sure you do not become dehydrated (lose too much liquid from your body). If you do become dehydrated you should see your doctor to correct this, before continuing with DIASTOP.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately. You should not take DIASTOP near, or at the time of giving birth. This is because diphenoxylate is chemically related to other medicines that can slow down the breathing of newborn infants.

Things you must not do

Be careful driving or operating machinery or performing jobs where you need to be alert until you know how DIASTOP affects you.

This medicine may cause drowsiness or dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

Do not drink alcohol or milk while you are taking this medicine. Drinking alcohol or milk may make your diarrhoea worse.

Side effects

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

This medicine helps most people with diarrhoea, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Feeling generally unwell
- Fever
- Tiredness, lack of energy, confusion, sleepiness
- Dizziness, restlessness, depression, hallucinations
- Headaches, feeling overexcited
- Tingling and numbness in hands and feet
- Gastrointestinal problems (vomiting, nausea, reduced appetite, constipation, abdominal pain and discomfort)
- Difficulty passing urine.

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Fast, slow or irregular heart beat
- Difficulty in breathing, wheeziness
- Swelling of the eyelids, face or lips
- Rash or itching (especially affecting your whole body)

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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

After using DIASTOP

Storage

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

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store DIASTOP or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

DIASTOP tablets are white, round tablets blank on both sides.

Ingredients

DIASTOP contains 2.5 mg of diphenoxylate hydrochloride and 0.025 mg of atropine sulphate as the active ingredients.

It also contains:

- Microcrystalline cellulose
- Pregelatinised maize starch
- Colloidal silicon dioxide
- Magnesium stearate.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: 0800 168 169

Date of Information

20 September 2010
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