

Package leaflet: Information for the patient

DIARZIL **10 mg/125 mg** tablets

Loperamide hydrochloride
Simeticone

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better after 2 days or if you feel worse.

What is in this leaflet?

1. What DIARZIL is and what it is used for?
2. What you need to know before you take DIARZIL?
3. How to take DIARZIL?
4. Possible side effects
5. How to store DIARZIL ?
6. Contents of the pack and other information

1. What DIARZIL is and what it is used for?

The tablets are used to treat a short lived attack of diarrhoea when it occurs with stomach cramps, bloating and wind.

The tablets contain two active ingredients:

- loperamide hydrochloride, which helps reduce diarrhoea by slowing down an overactive bowel. It also helps the body to absorb more water and salts from the bowel.
- simeticone, which breaks up the trapped wind in the bowel that causes cramps and bloating.

The tablets are used to treat a short-lived attack of diarrhoea when it occurs with stomach cramps, bloating and wind.

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2. What you need to know before you take DIARZIL?

Do not take DIARZIL:

- In children less than 12 years old.
- If you are allergic (hypersensitive) to loperamide hydrochloride, simeticone or any ~~of~~ the other ingredients of the tablets (see section 6).
- If you have a high temperature (e.g. above 38 °C) or blood in your stools.
- If you are having a flare up of an inflammatory bowel condition like ulcerative colitis.
- If you have severe diarrhoea after taking antibiotics.
- If you are constipated or your stomach appears swollen.

If any of these apply to you, get advice from a doctor or pharmacist without taking DIARZIL.

Warnings and precautions

Talk to your doctor or pharmacist before taking DIARZIL.

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- DIARZIL only treats the symptoms of diarrhoea. In some cases, the cause of your diarrhoea may require treatment, if symptoms persist or worsen, please contact your doctor. If you have severe diarrhoea as your body loses more fluid, sugars and salts than normal. You will need to replace the fluid by drinking more liquid than usual. Ask your pharmacist about special powders which replace the sugars and mineral salts.
- If you have AIDS and your stomach becomes swollen, stop taking the tablets immediately and contact your doctor.
- If you have liver disease. Check with your doctor before using taking the tablets. Some of the side-effects might be more troublesome.
- ~~If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This drug contains lactose and patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.~~

Children

Children under 12 years old must not take DIARZIL.

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Other medicines and DIARZIL

Talk to your doctor or pharmacist if you are taking have recently taken or might take any other medicines, any other medicines including:

- quinidine (used to treat abnormal heart rhythms or malaria)
- itraconazole or ketoconazole (antifungal medicines)
- gemfibrozil (used to treat high cholesterol)
- ritonavir (used to treat HIV infection and AIDS)
- desmopressin (used to control thirst and urine production in patients with diabetes insipidus)

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Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, because DIARZIL may interact with them.

Pregnancy and breast-feeding

Pregnancy: Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or, think that you are pregnant or planning to become pregnant.

Breast-feeding: Do not take this medicine if you are breast-feeding as small amounts of the medicine may get into your milk. Talk to your doctor about a suitable treatment.

Driving and using machines

This medicine may make you feel dizzy, tired or sleepy. If affected do not drive or operate machinery.

3. How to take DIARZIL

Always take this medicine exactly as your pharmacist has told you. Check with your pharmacist if you are not sure.

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Unless you received other instructions from your doctor, follow the following instructions

- Swallow the correct number of tablets whole with a drink of water.
- For oral use only.
- Do not use more than the stated dose.

Adults over 18 years old: Swallow two tablets initially, followed by one tablet after every loose stool (bowel movement). Do not take more than 4 tablets in a day. If you are no better after two days, stop taking the tablets and contact your doctor.

Adolescents (12 to 18 years): Swallow one tablet initially, followed by one tablet after every loose stool (bowel movement). Do not take more than 4 tablets in a day. If you are no better after two days, stop taking the tablets and contact your doctor.

Do not give the tablets to children less than 12 years old.

If you take more DIARZIL than you should

If you have taken too much DIARZIL, immediately seek the advice of a doctor or a hospital.
Symptoms may include: heart beat acceleration, irregular heart beat, changes in your heart beat (these symptoms may potentially have serious consequences and engage the vital prognosis), muscle stiffness, uncoordinated movements, drowsiness, difficulty to urinate, respiratory distress, dry mouth, constricting pupils, stomach aches, nausea, vomiting or constipation.

Children react more strongly to high doses of DIARZIL than adults. If a child takes too much or has any of the above mentioned symptoms, immediately contact a doctor.

If you have used or taken too much DIARZIL, immediately contact your doctor, pharmacist or a poison control center.

Too many tablets may make you feel drowsy, or make it difficult to think clearly or carry out normal activities. Your muscles may feel stiff or you may experience breathing difficulties. You may have a dry mouth or the pupils of your eyes may become small. You may have stomach pain, feel sick or vomit, be constipated or have difficulty passing water.
If you have taken too many DIARZIL, contact a doctor or nearest hospital.

If you forget to take DIARZIL

Take one tablet after the next loose stool (bowel movement). Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following stop using the medicine and seek immediate medical help:

Allergic reactions including swelling of the face, tongue or throat, difficulty swallowing, unexplained wheezing, shortness of breath which may be accompanied by skin rash or hives.

If you experience any of the following, stop using the medicine and talk to your doctor:

- difficulties passing water
- severe abdominal pain, abdominal bulging or swellingbloating or distension or fever which may be due to a blocked or enlarged bowel
- severe constipation

Other effects which may occur include:

Common side-effects (less than 1 in 10 but more than 1 in 100 people get these): headache, feeling sick, a change in the way some things taste.

Uncommon side-effects (less than 1 in 100 but more than 1 in 1000 people get these): drowsiness, dizziness, weakness, constipation, vomiting, indigestion, wind, dry mouth, rash.

Rare side effects (less than 1 in 1000 but more than 1 in 10 000 people get these): loss of consciousness or decreased consciousness, excessive contraction of the pupil of the eye, skin rash, which may lead to severe blistering and peeling of the skin, hives, itching, tiredness.

If you get any serious side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

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5. How to store DIARZIL

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 carton and blister. The expiry date refers to the last day of that month.

| Do not store above 30°C.

| Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What DIARZIL contains

The active substances ~~are~~ are: loperamide hydrochloride (2 mg per tablet) and simeticone (equivalent to 125 mg dimeticone per tablet).

The other ingredients are: tribasic calcium phosphate, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.

What DIARZIL looks like and contents of the pack

White tablets packed in PVC-PVDC/Aluminium blisters.

DIARZIL is available in boxes of 12 tablets.

DIARZIL® is a trademark

Property of Exphar s.a.

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