

Package leaflet: Information for the user

Dimor Comp 2 mg/125 mg tablets

loperamide hydrochloride, dimeticone

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 have 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 or if you feel worse after two days.

What is in this leaflet

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

1. What [to be completed nationally] is and what it is used for

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 gas bubbles in the bowel that causes cramps and bloating.

[to be completed nationally] is used in adults and adolescents aged 12 years and above, to treat a short-lived attack of diarrhoea when it occurs with stomach cramps, bloating and wind.

2. What you need to know before you take [to be completed nationally]

Do not take [to be completed nationally]

- In children less than 12 years old.
- If you are allergic to loperamide hydrochloride, simeticone or any of the other ingredients of this medicine (listed in 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking [to be completed nationally].

- [to be completed nationally] only treat 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 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 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 the tablets. Some of the side-effects might be more troublesome.
- Do not take this product for anything other than its intended use (see section 1) and never take more than the recommended amount (see section 3). Serious heart problems (symptoms of which include fast or irregular heartbeat) have been reported in patients who have taken too much loperamide, one of the active ingredients in [to be completed nationally].

In acute diarrhoea, the symptoms usually disappear within two days. If symptoms persist after this period, stop taking this medicine and contact your doctor.

Children

Children under 12 years of age must not take [to be completed nationally].

Other medicines and [to be completed nationally]

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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)

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription because [to be completed nationally] may interact with them.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

[to be completed nationally] is not recommended if you are breast-feeding. Small amounts of the medicine could end up in your milk.

Driving and using machines

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

[to be completed nationally] contains sodium

This medicine contains less than 1 mmol of sodium (23 mg) per tablet, that is, it is essentially 'sodium-free'.

3. How to take [to be completed nationally]

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Swallow the correct number of tablets with a drink of water.
- Do not use more than the stated dose.
- The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Use in adults over 18 years old

Swallow 2 tablets initially, followed by 1 tablet after every loose stool (bowel movement). Do not take more than 4 tablets in a day. If your symptoms persist after two days, stop taking the tablets and contact your doctor.

Use in adolescents aged 12 to 18 years old

Swallow 1 tablet initially, followed by 1 tablet after every loose stool (bowel movement). Do not take more than 4 tablets in a day. If your symptoms persist after two days, stop taking the tablets and contact your doctor.

Use in children and adolescents less than 12 years old

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

If you take more [to be completed nationally] than you should

If you have taken too many [to be completed nationally], immediately contact a doctor or hospital for advice. Symptoms may include: increased heart rate, irregular heartbeat, changes to your heartbeat (these symptoms can have potentially serious, life-threatening consequences), muscle stiffness, uncoordinated movements, drowsiness, difficulty urinating, weak breathing, dry mouth or the pupils of your eyes may become small, stomach pains, feel sick or vomit or be constipated.

Children react more strongly to large amounts of [to be completed nationally] than adults. If a child takes too much or shows any of the above symptoms, call a doctor immediately.

If you forget to take [to be completed nationally]

Take 1 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 medicine, 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.

Not known (frequency cannot be estimated from the available data): Upper abdominal pain, abdominal pain that radiates to back, tenderness when touching the abdomen, fever, rapid pulse, nausea, vomiting, which may be symptoms of inflammation of the pancreas (acute pancreatitis).

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 swelling or fever which may be due to a blocked or enlarged bowel
- Severe constipation

Other effects which may occur include

Common (may affect up to 1 in 10 people):

- Headache
- Feeling sick
- A change in the way some things taste.

Uncommon (may affect up to 1 in 100 people):

- Drowsiness
- Dizziness
- Weakness
- Constipation
- Vomiting
- Indigestion
- Wind
- Dry mouth
- Rash

Rare (may affect up to 1 in 1,000 people):

- 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
- Muscle tension
- Difficulty coordinating movement

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 listed in Appendix V]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [to be completed nationally]

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

This medicinal product does not require any special storage conditions.

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 [to be completed nationally] contains

The active substances are: loperamide hydrochloride (2 mg per tablet) and simeticone (measured as 125 mg dimeticone per tablet).

The other ingredients are: microcrystalline cellulose (E460), sodium starch glycolate, hypromellose (E464), povidone (E2101), calcium phosphate (E341), mannitol (E421) and magnesium Stearate (E572).

What [to be completed nationally] looks like and contents of the pack

The tablets are white to off white caplets with “LO-SI” debossed on one side and ‘2’ & ‘125’ debossed on the opposite side at either side of a scoreline

Each pack contains 6, 8, 10, 12, 15, 16, 18, 20 or 30 tablets in blister strips.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

[to be completed nationally]

Manufacturer

Laboratorios Alcala Farma, S.L.
Avenida de Madrid 82
28802 Alcalá de Henares, Madrid
Spain

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Winkelskamp 6
7255 PZ Hengelo (Gld)
The Netherlands

This leaflet was last revised in 2024-03-08