

Package leaflet: information for the user

Anti-diarrheal HTP Loperamide HCl 2 mg, capsules

loperamide hydrochloride

Read carefully the entire leaflet before you start using this medicine, because there is important information in it for you.

Use this medicine always exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need it later again.
- Do you still have questions? Then contact your pharmacist.
- Do you experience any of the side effects listed in section 4? Or do you experience a side effect that is not in this leaflet? Then contact your doctor or pharmacist.
- Does your complaint after 2 days not get better, or does it even get worse? Then contact your doctor.

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1. What is Anti-diarrheal HTP Loperamide HCl 2 mg and for what is this medicine used?

Anti-diarrheal HTP Loperamide HCl contains loperamide hydrochloride. This is a substance that reduces the strong propulsive movements of the intestine. This ensures the effect of this medication against diarrhea. This medication works only where it is needed, namely in the intestine. Diarrhea usually stops within a few hours.

Anti-diarrheal HTP Loperamide HCl capsules are used against acute or chronic diarrhea in adults and children from 8 years. Acute diarrhea begins suddenly and is usually over within a week. Chronic diarrhea is prolonged. This medication is used to combat diarrhea itself. It treats the symptoms, not the cause of the diarrhea. If the cause of the diarrhea is known, it must also be treated.

Is acute diarrhea after 2 days not better, or does it even get worse? Then contact your doctor.

2. When may you not use this medicine or must you be extra careful with it?

When may you not use this medicine?

- You are allergic to any of the substances in this medicine. These substances can be found in section 6.
- You must never give this medicine to children younger than 2 years.

- The capsules are not suitable for children younger than 8 years (see under 'When should you extra careful be with this medicine?').
- Do not use this medicine if you think that the cause of the diarrhea a poisoning, for example with a heavy metal (such as mercury, lead or cadmium), could be.
- You may not use this medicine if you have a 'megacolon'. That is a severely dilated large intestine; a serious situation that can occur in patients with disease of Hirschsprung, the disease of Crohn or colitis ulcerative, to recognize by a very painful swollen abdomen, fever and an accelerated heartbeat.
- Do not use this medicine if you actually have a constipation of the intestines, causing some watery stool 'leaks'. This occurs in certain bowel conditions intestinal disorders.
- Do not use this medicine if you have persistent abdominal pain, if you have a high fever and/or if your stool mucus and/or blood contains. These symptoms can occur due to a food poisoning or due to an infection or inflammation of the large intestine.
- Use this agent not if you have a bacterial infection of the large and/or small intestine caused by invasive organisms, including Salmonella, Shigella, Campylobacter, has.
- Use this medicine not if you have a severe intestinal inflammation (for example colitis ulcerative or pseudomembranous colitis due to the use of certain antibiotics).
- Do not use this medicine in all cases where the normal bowel movements must not be allowed to become suppressed. The administration must immediately be discontinued in constipation or abdominal swelling.

When must you be extra careful with this medicine?

Contact your doctor or pharmacist before you use this medicine.

With this medicine only the diarrhea itself is self-addressed, but not the cause of it. If the cause is known, then it must be treated separately, if possible. In case of doubt always consult your doctor.

Take this medicine not for a different condition than for which it is intended (see section 1) and never take more than the recommended amount (see section 3). Serious heart problems (symptoms such as a rapid or irregular heart rate) have been reported in patients who have taken too much loperamide, the active ingredient of Antidiarrheal HTP Loperamide HCl, have taken.

- If you have diarrhea, you lose a lot of fluid (dehydration). With that fluid also important other substances are lost. Dehydration can be: a dry mouth, dizziness and/or vomiting.
Risk of dehydration exists especially in young children and the elderly. In them there must therefore be the first measure in diarrhea: the fluid in the body is replenished and at level maintained. That means: drink plenty, and replenish sugar and salt. You can at the pharmacy or drugstore get a special salt-sugar mixture (ORS called) that in water must be dissolved. Ask your doctor or pharmacist about this for advice.
- Do you have AIDS and are you being treated for diarrhea with this medication? Stop using this medication as soon as you experience any symptoms of a swollen abdomen. In that case contact with your doctor. In people with AIDS and a severe intestinal infection (infectious colitis) who used loperamide (the substance that also in this medicine contains), are some cases reported of constipation with an increased risk for toxic

megacolon. That is a strong dilated large intestine, to recognize by a very painful distended abdomen, fever and a rapid heartbeat.

- Does your liver function less well? Then contact your doctor before you use this medicine .. you need to be closely monitored become if you this medicine use. Moreover may you perhaps a different dose need to side effects on the nervous system to avoid.

Children

Children aged 2 to 8 years may use the substance loperamide only use on prescription from a doctor or under supervision of a doctor. Always follow always the the dosage prescribed by the doctor has prescribed. Moreover are Antidiarrheal HTP Loperamide HCl capsules not suitable for children younger than 8 years. They must for example drink with loperamide use to the correct (lower) dose to be able to take.

When must you stop with this medicine?

- Stop with this medicine as soon as your stool becomes firmer or as soon as there is more than twelve hours hour no stool anymore has occurred.
- Do you use this medicine for acutediarrhea ? If the diarrhea does not decrease 48 48 after you have started with the use of this medicine, stop using the medicine and contact your doctor. If you this medicine
- If you this drug not on prescription of a doctor used, you should never longer than 14 days use. Are your symptoms after 14 days still not disappeared, contact your doctor. If you this medicine do use on prescription of your doctor, then will the doctor the dose adjust if the complaints after 14 days still not disappeared are.
- If you experience get of constipation or a bloated stomach, stop immediately with the use of this medicine and contact your doctor.
- If you this medicine use for chronic diarrhea, then will your doctor after some time try or the dosage in you can be reduced or that with the treatment can be stopped.

Keep you carefully to the recommended dosage. If you exceed the recommended dosage exceedsthere is a risk of constipation . Youcan recognize this by the constipation, a bloated abdomen and the leakage of watery stools.

Are you taking any othermedications

? Are next to Antidiarrheal HTP Loperamide HCl still other medications, have you that shortly ago done or is the possibility that you in the near future other medicines go use? Tell that then your doctor or pharmacist.

Inform your doctor or pharmacist of the situation if you one of the following medicines take:

- medicines with similar action in the body, because expected is that they enhance the effect of this drug can strengthen.
- medicines that intestinal transit accelerate, because expected is that they the effect of this drug can reduce reduce.
- againstagainst HIV infections).
- quinidine (treat of arrhythmias).
- oral desmopressin (treat of urinaryincontinence).
- itraconazole or ketoconazole (treat of fungal infections).
- gemfibrozil (lowering of cholesterol).

Pregnancy and breastfeeding

Are you pregnant, do you think you are pregnant, do you want to become pregnant, do you want to pregnant become of gives you breastfeeding? Then contact your doctor or pharmacist before you this medicine use.

Pregnancy

The benefits of a treatment with this medication must be weighed against the potential risks, before this medication is used during the pregnancy, in the particularly during the first trimester. Consult first your doctor.

Breastfeeding

The substance that ensures the effect of this medicine drug enters in very small quantities into the breast milk .. you should not use this medicine if you are breastfeeding breastfeeding gives. If you still are going to use, then stop breastfeeding. Consult about this as necessary with your doctor.

Driving ability and the use of machines

When use of this medicine may fatigue, dizziness or drowsiness occur. Before you start driving or dangerous machines operate operate, must you check if that applies to you the case is.

Antidiarrheal HTP Loperamide HCl 2 mg contains lactose

Has your doctor told that you some sugars not tolerate? Then contact your doctor before you this medicine take.

3. How use you this medication?

Use this medicine always exactly as described in this leaflet or as your doctor or pharmacist you has told you. Doubt you about the correct use? Then contact your doctor or pharmacist.

This medicine is intended for adults and children older than 8 years. De recommended dosage is:

Adults with acute (sudden) diarrhea

Start with 2 capsules (4 mg) at once. Take then after each subsequent loose stool 1 capsule (2 mg), as long as the diarrhea lasts. Never take more than 8 capsules (16 mg) in one day.

Adults with chronic (long-term) diarrhea

Start with 2 capsules (4 mg) per day. This dose must be adjusted, until you have 1 to 2 times per day solid stool .Usually this is achieved with 1 to 6 capsules (2 to 12 mg) per day. Never take more than 8 capsules (16 mg) in one day.

Use in children

Children older than 8 years with acute diarrhea

Start with 1 capsule (2 mg). Give afterwards after each subsequent loose stool 1 capsule (2 mg), as long as the diarrhea lasts. The number of capsules that a child on one day in may take, is dependent on the body weight of the child, see for this below table. Never give a child more than 8 capsules (16 mg) in one day.

Children older than 8 years with chronic diarrhea

Start with 1 capsule (2 mg) per day. This dose must be adjusted, until the child 1 to 2 times per day solid stool has. Usually is this achieved with 1 to 6 capsules (2 to 12 mg) per day. The number capsules that a child per one day may take take, is dependent on the body weight of the child, see for this the following table. Give a child never more than 8 capsules (16 mg) in one day.

Body weight in kilogram (kg)	Maximum number Antidiarrheal HTP Loperamide HCl capsules per day
20 – 27 kg	3 capsules
27 – 34 kg	4 capsules
34 – 40 kg	5 capsules
40 – 47 kg	6 capsules
47 – 54 kg	7 capsules
more than 54 kg	8 capsules

Children from 2 to 8 years

This medicine may not be administered to children younger than 8 years , thereare however indeed products products with a lower strength and in other dosage form, which more suitable are for this age group (for example a syrup), available.

Elderly

There is no adjustment of the dose required for elderly.

Reduced renal function

There is no adjustment of the dose required in patients with a reduced renal function.

Reduced hepatic function

This medication must be used cautiously in patients with a reduced hepatic function liver function in relation to the risk of side effects (see section 2).

Method of intake

Swallow the capsules whole with some water. Have

you taken too much of this medication used?

Overdose means that you or someone in your surroundings more of this medication has taken then is indicated in this leaflet (see under "How to use this medicine ?").If you

have taken too much Anti-diarrheal HTP Loperamide HCl have taken in, then immediately contact your doctor or go to the hospital for advice. The following symptoms may occur: increased heart rate, irregular heart rate, changes in your heart rate (these symptoms can potentially serious and even life-threatening consequences have), muscle stiffness, uncoordinated movements, drowsiness, problems urinating , aweak breathing , nausea, vomiting, abdominal pain, abdominal pain, abdominal cramps, constipation, dry mouth or small pupils.

Children react more strongly to large amounts Antidiarrheal HTP Loperamide HCl than adults. If one child too much takes or one of the above mentioned symptoms shows, call immediately a doctor.

Did you forget this medicine to use?

If you have forgotten this medicine in to take, do that then anyway, unless you a normal bowel movement have had. Take no double dose to make up for a missed dose in catch. Make sure in any case that there are at least two hours between two intakes is.

Do you still other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine can also this medicine have side effects , althoughnot everyone experiences them . Seek immediate.

help immediately medical help at:

Pain in the upper abdomen, abdominal pain that radiates to the back, tenderness at touch of the abdomen, fever, rapid heart rate, nausea or vomiting. This can be symptoms of inflammation of the pancreas (acute pancreatitis). If you experience any of these from this side effects, then stop the use of the medication and call immediately medical help in. The frequency of these side effects is not known (may with the available data not can be determined).

Other possible side effects are listed below.

Common (occur in less than 1 in 10 users users) Nervous system disorders: Headache, dizziness
Gastrointestinal disorders: Constipation, nausea, flatulence

Sometimes (occur in less than 1 in 100 users)Gastrointestinal disorders

Gastrointestinal disorders: Abdominal pain, discomfort in the abdomen, dry mouth, pain in the upper abdomen, vomiting, heartburn

Skin- and subcutaneous disorders: Skin rash

Rarely (occur in less than 1 in 1,000 users)Gastrointestinal disorders Gastrointestinal disorders: abdomen ,taste disorders Unknown

(can (can with the available data not can be determined)

Immune system disorders: Hypersensitivity reaction, severe allergic reactions (anaphylactic reaction (including anaphylactic shock) and anaphylactoid reaction)

Nervous system disorders: Drowsiness, loss of consciousness, reduced consciousness (stupor), weakened consciousness, increased muscle tension (hypertonia), coordination disorders Eye disorders: Constriction of the pupil (miosis)

Gastrointestinal disorders: Reduced or absent bowel passage (ileus and paralytic ileus), enlargement of the thick intestine (megacolon), painful tongue (glossodynia)

Skin- and subcutaneous disorders: Toxic-allergic reaction at the level of the skin and mucous membranes characterized by redness, formation of blisters and detachment of the epidermis (bullous eruption (also Stevens-Johnsonsyndrome, Lyell-syndrome and erythema multiforme)), swollen face, hives, itching

Renal and urinary disorders: Retention of urine in the bladder due to a disturbed bladder emptying (urinary retention)

General disorders: Fatigue

The reporting of side effects

Do you experience side effects, please contact your doctor or pharmacist. This applies also for possible side effects that are not in this leaflet. You can report side effects also directly report via the Dutch Side Effects Centre Lareb, website: www.lareb.nl. By side effects to report, can you help more information to obtain about the safety of this medicine.

5. How store you this medicine?

Keep out of sight and reach of children .. below 30 °C. Do not use this medication any longer more after the expiry date. It is to find on the packaging after "Do not use after :" or "Exp.:". There is a month and one year. The last day of that month is the expiry date.

After opening the tablet container still 12 months shelf life. The container carefully closed keep.

Rinse medicines not through the sink or the toilet and throw them not in the trash. Ask your pharmacist what to do with medicines must do that you not anymore use. They are then in a responsible manner destroyed and do not enter the environment ..

6. Content of the packaging and other information What substances are in this medicine?

- The active substance in this medicine is loperamide hydrochloride. Each capsule contains 2 mg loperamide hydrochloride.
- The other ingredients in this medicine are lactose monohydrate (see section 2), corn starch, talc, magnesium stearate, gelatin, titanium dioxide (E 171), quinoline yellow (E104), indigotine (E132), iron oxide yellow (E172) and iron oxide black (E172).

How does Antidiarrheal HTP Loperamide HCl 2 mg look like en how much is in a package?

Antidiarrheal HTP Loperamide HCl 2 mg, capsules are opaque dark green/gray and contain a white powder.

The product is packaged in blister packaging (push-through strips) of 10 capsules with multiples of 10 pieces in a box or in a tablet container with 30, 50, 100, 150, 200, 250, 500, 1000, 1500, 2000, 2500 or 5000 capsules.

Not all mentioned pack sizes are in the market introduced.

Holder of the authorization for placing on the market and manufacturer Holder

of the authorization license for the in the market introduction
Healthypharm B.V. Van de Reijtstraat 31-E 4814 NE Breda Netherlands

Manufacturer
Centrafarm Services B.V.
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In the register registered under

RVG 20642=15140, Antidiarrheal HTP Loperamide HCl 2 mg, capsules.

This leaflet is for the last approved in June 2022.

More information over this medication is available on the website