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1.3.1 spc-label-pl - common-pl - 8,236 (NL/H/2731/001)		20170510
LOPERAMIDE HYDROCHLORIDE+SIMETHICONE 2 MG + 125 MG TABLET		722-1892.00

Package leaflet: Information for the user

{Nationally completed name 2mg/125mg 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 or if you feel worse after two days.

What is in this leaflet

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

1. What {nationally completed name tablets} 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 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.

The tablets also contain simeticone, which breaks up the trapped wind in the bowel that causes cramps and bloating.

2. What you need to know before you take {nationally completed name tablets}

Do not take {nationally completed name tablets}

- 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

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Talk to your doctor or pharmacist:

- {nationally completed name tablets} 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 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 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, the active ingredient in {nationally completed name tablets}.

Other medicines and {nationally completed name tablets}

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, because {nationally completed name tablets} may interact with them.

In particular tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:

- Quinidine (used to treat abnormal heart rhythms or malaria)
- Itraconazole or Ketoconazole (an antifungal medicine)
- Gemfibrozil (used to treat high cholesterol)
- Ritonavir (used to treat HIV infection and AIDS)
- Desmopressin (used in the treatment of diabetes insipidus and bedwetting)

Pregnancy and breast-feeding

- Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant, think you are pregnant or planning to become pregnant.
- 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 {nationally completed name tablets}

- 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.
- For oral administration

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- Swallow whole with a drink
- 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 two tablets initially, followed by one tablet after every loose stool (bowel movement). Do not take more than 4 tablets in a day, limited to no more than 2 days. If you are no better after two days, stop taking the tablets and contact your doctor.

Use in adolescents from 12 to 18 years old

Swallow one tablet initially, followed by one tablet after every loose stool (bowel movement). Do not take more than 4 tablets in a day, limited to no more than 2 days. If you are no better after two days, stop taking the tablets and contact your doctor.

Use in children

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

If you take more {nationally completed name tablets} than you should

If you have taken too many {nationally completed name tablets}, 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, or weak breathing. Too many tablets may make it difficult to think clearly or carry out normal activities. You may have a dry mouth or the pupils of your eyes may become small. You may have stomach pain, feel sick or vomit or be constipated.

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

If you forget to take {nationally completed name tablets}

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.

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

- Difficulties passing water
- Stomach pain or swollen stomach
- Severe constipation

Other effects which may occur include

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

- Feeling sick, or a change in the way some things taste.

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

- Drowsiness, constipation, rash

Other effects:

- Vomiting, indigestion, constipation, wind, dizziness, loss of consciousness or decreased consciousness

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 {nationally completed name tablets}

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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment

6. Contents of the pack and other information

What {nationally completed name tablets} contain

The active ingredients 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 {nationally completed name tablets} look like and contents of the pack

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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

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7255 PZ Hengelo (Gld)
The Netherlands

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Otto-von-Guericke-Allee 1, 39179 Barleben
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<This medicinal product is authorised in the Member States of the EEA under the following names:>

This leaflet was last revised in <{MM/YYYY}>