PRIMODIUM CAPSULES

Loperamide hydrochloride (2mg)

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What Primodium is used for

For control and symptomatic relief of short and long term diarrhoea associated with inflammatory bowel disease.

How Primodium works

Loperamide inhibits movement of the intestines by direct effect on the muscles of the intestinal wall.

Before you use Primodium

- When you must not use it
- you are allergic to loperamide or any of the other ingredients of Primodium.
- you are constipating.

- Before you start to use it

Please inform your doctor/pharmacist if:

- you have lost body fluids and salts through diarrhoea especially in young children with severe diarrhoea.
- you have very smelly stools, blood or pus in your stools, stomach pain, or a fever.
- you have liver disease.
- you have inflammation of the intestines (ulcerative colitis).
- you are pregnant and breastfeeding.

- <u>Taking other medicines</u>

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

How to use Primodium

- How much to use

Adults: 4mg, initially, followed by 2mg after each loose stool, not exceeding 16mg daily. Long term diarrhoea: initial: 4mg followed by 2mg after each loose stool until diarrhoea is controlled. Maintenance: 4 – 8 mg a day in single or divided daily doses as needed. Children: as directed by physician. Follow all directions given to you by your doctor and

pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Primodium for as long as your doctor recommends.

- If you forget to use it

Consult the doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Depression of the CNS may be seen. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Primodium

- Things you must do
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Primodium.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give product name to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Primodium can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Abdominal pain, constipation, dizziness, dry mouth, tiredness, nausea and vomiting and allergic reactions may occur occasionally.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website <u>portal.bpfk.gov.my</u> (Consumers → Reporting)

Storage and Disposal of Primodium

- <u>Storage</u>

Store in cool, dry place below 30°C. Protect from light. Keep out of reach and sight of children.

- <u>Disposal</u>

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 to protect the environment.

Product description

- What it looks like

Dark green opaque cap and light grey opaque body capsules.

- <u>Ingredients</u>
- Active ingredient: loperamide hydrochloride
- Inactive ingredients: lactose monohydrate, cornstarch and magnesium stearate.
- <u>MAL number</u> MAL19900404AZ

Manufacturer and Product Registration Holder

Prime Pharmaceutical Sdn. Bhd. 1505, Lorong Perusahaan Utama 1 Taman Perindustrian Bukit Tengah 14000 Bukit Mertajam, Penang, Malaysia.

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