REXIMIDE CAPSULE

Loperamide hydrochloride (2mg)

What is in the leaflet

- 1. What Reximide is used for
- 2. How Reximide works
- 3. Before you use Reximide
- 4. How to use Reximide
- 5. While you are using it
- 6. Side effects
- 7. Storage and Disposal of Reximide
- 8. Product Description
- 9. Manufacturer and Product Registration Holder
- 10. Date of Revision

What Reximide is used for

This medicine is used to treat:

- Sudden short term attacks of diarrhoea
- Chronic diarrhoea
- Reducing the volume of discharge in certain people (e.g. ileostomies, colostomies, and other intestinal resections)

How Reximide works

Reximide contains the active ingredient Loperamide hydrochloride. Loperamide hydrochloride belongs to a group of medicines which helps reduce diarrhoea by slowing down an overactive bowel.

It also helps the body to absorb more water and salts from the bowel.

Before you use Reximide

When you must not take it

Do not take this medicine if you have an allergy to:

 Loperamide hydrochloride, the active ingredient, or to any of the other ingredients listed at the end of this leaflet Do not take Reximide if:

- You are constipated or have any condition which may cause constipation or where constipation should be avoided
- You have severe diarrhoea after taking antibiotics
- Your child is less than 12 years
- You suffer from colitis (inflammation of the colon) or any other inflammatory bowel disease.
- You have dysentery (disease caused by eating and drinking contaminated food and water) and you may have a fever and blood in your stools

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. Your doctor can discuss with you the risks and benefits involved.

Loperamide should be used in pregnant women only when clearly needed. Loperamide are not recommended in breastfeeding mothers.

Tell your doctor if you have any of the following health problems:

- Liver disease
- Kidney disease
- Glaucoma (high pressure in the eyes)
- Urinary bladder neck obstruction
- Stomach outlet obstruction
- Gastric retention or decreased intestinal movement

If you have not told your doctor about any of the above, tell him/her before you start taking Reximide.

- Taking other medicines

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

Some medicines and Reximide may interfere with each other such as tranquilizer and alcohol.

How to use Reximide

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor or pharmacist for help.

- How much to use

The dosage of Reximide depends on the condition it is being used to treat.

Acute diarrhoea

The recommended initial dose is 2 capsules followed by one capsule after each episode of diarrhoea.

Chronic diarrhoea and reduction in volume of discharge

Your doctor will tell you how many capsules to take. This will depend on how serious your condition is.

The recommended initial dose is 2 capsules followed by one capsule after each episode of diarrhoea until diarrhoea is controlled, after which the dosage should be reduced to meet individual requirements.

Never take more than 8 capsules in any 24 hour period.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

- When to use it

Take Reximide Capsule as your doctor has prescribed.

- How long to use it

Continue taking your medicine for as long as your doctor tells you.

If you forget to use it

You should only take this medicine as required following the dosage instructions given carefully.

If you forget to take a dose, take a dose after the next loose stool (bowel movement).

Do not take a double dose to make up for a forgotten dose.

- <u>If you use too much</u> (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Reximide.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using it

- Things you must do

If you become pregnant while taking this medicine, tell your doctor immediately.

- Things you must not do

Do not take Reximide to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how Reximide affects you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

These are the more common side effects of Reximide.

- Flatulence (wind)
- Constipation
- Nausea
- Abdominal pain

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

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

Storage and Disposal of Reximide

- <u>Storage</u>

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Keep your medicine in a place where the temperature stays below 25°C. Protect from light.

Do not store Reximide or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

- Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

- What it looks like

Reximide Capsule 2mg – A green / white, capsule with marking 'DUO 861'.

- Ingredients

Active ingredient

• Loperamide hydrochloride

Inactive ingredients:

- Lactose
- Magnesium stearate
- <u>MAL number</u> Reximide Capsule 2mg MAL19890163AZ

Manufacturer

Duopharma (M) Sdn. Bhd. (42491-M) Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

Duopharma (M) Sdn. Bhd. (42491-M) Lot. 2599, Jalan Seruling 59, Kawasan 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan, Malaysia.

Date of Revision

01/09/2015

Serial Number BPFK(R4/1)010915/00291