ROTIFAR TABLET

Loratadine (10mg)

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What Rotifar is used for

Rotifar relieves symptoms associated with allergic rhinitis (allergic inflammation of the nasal airways), such as sneezing, runny or itchy nose, and burning or itchy eyes.

Rotifar can also be used to relieve symptoms associated with a skin condition called urticaria; these symptoms include itching, redness and lumps on the skin called hives.

How Rotifar works

Rotifar belongs to a class of medicines known as antihistamines. Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine, which is produced by the body.

Your doctor may have prescribed Rotifar for another reason. Ask your doctor if you have any questions about why Rotifar has been prescribed for you.

Before you use Rotifar

- When you must not use it

Do not take Rotifar if you are allergic to loratadine or any of the tablet ingredients listed at the end of this leaflet. If you have an allergic reaction, you may get a skin rash, or experience difficulty in breathing or faintness.

Do not use Rotifar if you are pregnant or breastfeeding unless you and your doctor or pharmacists have discussed the risks and benefits involved.

Do not use Rotifar in children less than 2 years old.

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 you are not sure whether you should start taking Rotifar, talk to your doctor or pharmacist.

- Before you start to use it

Tell your doctor or pharmacist if you have allergies to:

- Any other medicines
- Any other substances, such as foods, preservatives or dyes.

Inform your doctor if you have liver disease or any other medical conditions.

If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine. Rotifar is not recommended in pregnancy or breastfeeding.

- Taking other medicines

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

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Rotifar.

How to use Rotifar

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 pack, ask your doctor or pharmacist for help.

- How much to use

Your doctor or pharmacist will tell you how much Rotifar you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

- For adults and children over 12 years is one tablet (10mg) daily.
- For children 2 to 12 years of age, weighing over 30 kg is one tablet (10mg) daily.
- For children 2 to 12 years of age, weighing less than 30 kg is half a tablet daily (5 mg).
- Do not used Rotifar for children under 2 years of age.
- If you have severe liver problems;
 a lower initial (5 mg) daily is recommended.

- When to use it

It does not matter if you take Rotifar before or after food. If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- How long to use it

Rotifar should improve your symptoms, but as with all medicines people may find it does not work for them. Continue to taking Rotifar for as long as the doctor recommends. If your symptoms have not improved, speak to your doctor or pharmacist.

- If you forget to use it

If you forget to take a dose, take it as soon as you remember it and then take the next dose at the right time.

Do not take a double dose of Rotifar to make up for the dose that you missed.

- If you use too much (overdose)

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your doctor or pharmacist immediately. Take the container and any remaining tablets with you to show the doctor. Signs of an overdose include sleepiness, fast heart beat and headache.

While you are using it

- Things you must do

You should only take the dose of Rotifar that is directed by the doctor or pharmacist.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Rotifar.

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking Rotifar.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Rotifar.

- Things you must not do

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

Do not take Rotifar to treat any other complaints unless your doctor or pharmacist tells you to.

- Things to be careful of

Rotifar do not cause drowsiness in most people. However, you should not drive or carry out skilled tasks, such as using machinery, until you are certain that you are unaffected in this way.

Make sure you know how you react to Rotifar before you drive a car, operate machinery, or do anything else that could be dangerous if you are feeling drowsy. If this occurs do not drive.

Be careful when drinking alcohol while taking Rotifar. Your doctor may suggest you avoid alcohol while you are being treated with Rotifar.

Side Effects

Like all medicines, Rotifar can cause side effects, although not everybody gets them. Stop taking Rotifar and contact your doctor at once if you notice signs of:

 an allergic reaction: swelling of the face, lips, tongue or throat, narrowing of the airways causing difficulty breathing, shock, collapse, rash, itching.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

- Nervous system: tiredness, sleepiness, headache, dizziness.
- Feeling or being sick, dry mouth.
- Liver: abnormal liver function (seen in blood tests).
- Skin: hair loss (alopecia).

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effect or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-7883 5550, or visiting the website portal.bpfk.gov.mv (Consumers – Reporting).

Storage and disposal of Rotifar

- Storage

Keep Rotifar tablets in a cool dry place where the temperature stays below 25°C. Protect from light.

Keep your Rotifar in the pack until it is time to take them. If you take the tablets out of the pack, they may not keep well.

Do not store Rotifar or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills. 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.

- <u>Disposal</u>

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

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

A white to off-white, oval shape tablet with a score line on one side and plain on the other side.

- <u>Ingredients</u>

Active Ingredient:

Each Rotifar Tablet contains 10mg of Loratadine.

Inactive Ingredients

- Croscarmellose Sodium
- Silicon Dioxide
- Lactose
- Magnesium Stearate
- Microcrystalline Cellulose
- <u>MAL Number</u> MAL12030005AC

Manufacturer

UPHA PHARMACEUTICAL MFG. (M) SDN BHD (53667-M) Lot 2&4, Jalan P/7, Section 13, Bangi Industrial Park, 43650 Bandar Baru Bangi, Selangor Darul Ehsan

Product Registration Holder

DUOPHARMA (M) SDN BHD (42491 M) Lot 2599, Jalan Seruling 59 Kaw 3, Taman Klang Jaya, 41200 Klang, Selangor Darul Ehsan.

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