

ROVANDIA TABLET

Rosiglitazone (4mg)

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What Rovandia is used for

This medicine is used to treat patients with type 2 diabetes mellitus. Rovandia can be used alone (monotherapy) or together with other anti-diabetic medicines, when diet and exercise is not enough to treat your diabetes.

How Rovandia works

Rovandia contains the active ingredient Rosiglitazone. It belongs to a group of medicine called thiazolidinedione.

Rovandia can help your body respond better to insulin made in your body. It does not cause your body to make more insulin.

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

Before you use Rovandia

- When you must not take it

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

- Rosiglitazone, the active ingredient

- any of the other ingredients listed at the end of this leaflet

Do not take Rovandia if:

- you have heart failure or have had heart failure in the past
- you are being treated for angina or having a heart attack.

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 have or have had any of the following medical conditions:

- Heart failure
- Swelling or pain of legs and feet
- Eye disorders
- Angina

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

If you have not told your doctor about any of the above,

tell him/her before you start taking Rovandia.

- 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 Rovandia may interfere with each other.

These include:

- CYP2C8 inhibitors (e.g. gemfibrozil)
- CYP2C8 inducers (e.g. rifampicin)

These medicines may be affected by Rovandia or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to use Rovandia

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 Rovandia depends on the condition it is being used to treat.

Take Rovandia as directed by your doctor or pharmacist.

The usual starting dose of Rovandia is 4 mg per day. If necessary, your doctor may increase this dose up to 8 mg per day, taken as a single dose or as two doses to be taken during the day (eg. one in the morning and one in the evening).

Do not take more tablets than your doctor has recommended.

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

Use in children:

There is no information available on the use of Rovandia in people under 18 years of age, therefore its use in these patients is not recommended.

- When to use it

Rovandia can be taken before or after meals. It is best to take the tablets at the same time each day.

- How long to use it

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

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

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.

- If you use too much (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 Rovandia.

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

Always follow your doctor's instructions carefully.

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Rovandia.

Tell your doctor if you become pregnant while taking Rovandia.

If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking Rovandia.

- Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not take Rovandia 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 Rovandia affects you.

However, Rovandia is not expected to affect your ability to drive a car or operate machinery.

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.

Rovandia may increase the risk of heart attack or heart failure in some patients. You must tell your doctor immediately if you develop any of the following:

- rapid increase in weight
- shortness of breath
- swelling of legs and feet
- chest 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 website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Rovandia

- Storage

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 30°C. Protect from light.

Do not store Rovandia 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

A triangle, film-coated orange coloured, embossed with CCM on one side and plain on the other side tablet.

- **Ingredients**
Active ingredient
- Rosiglitazone

Inactive ingredients:

- Pink colouring
- Lactose
- Microcrystalline cellulose
- Sodium starch glycolate
- Magnesium stearate
- Water

- **MAL number**

MAL11010009A

Manufacturer

UPHA PHARMACEUTICAL
MFG (M) SDN BHD (53667-
M)

Lot 2&4, Jalan P/7, Section 13,
Bangi Industrial Park, 43650,
Selangor Darul Ehsan

Product Registration Holder

CCM PHARMACEUTICALS
SDN BHD (277454-W)

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Date of Revision

3/12/2013