

# AXCEL ROSIGLITAZONE TABLET

Rosiglitazone 4/8mg

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## WHAT AXCEL ROSIGLITAZONE TABLET IS USED FOR

Axcel Rosiglitazone Tablet is used as an adjunct to diet and exercise to improve blood glucose control in patients with type 2 diabetes mellitus.

## HOW AXCEL ROSIGLITAZONE TABLET WORK

Rosiglitazone, a member of the thiazolidinediones class of antidiabetic agents, improves blood glucose control by improving insulin sensitivity.

## BEFORE YOU USE AXCEL ROSIGLITAZONE TABLET

### When you must not use it

Do not take Axcel Rosiglitazone Tablet if:

- If you are having allergy or hypersensitive to rosiglitazone or any other ingredient of the preparation.
- If you are having NYHA Class I to IV heart failure or history of cardiac failure.
- If you are having ischaemic heart disease (a condition where blood flow to the heart reduced).
- If you are having Acute Coronary Syndrome like chest pain.
- If you are having heart attack.
- If it is not prescribed by a qualified doctor or pharmacist for you.

- Do not take Axcel Rosiglitazone Tablet if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not take Axcel Rosiglitazone Tablet if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

### Before you start to use it

Tell your doctor if:

- If you are allergic to any medicines, food and dyes.
- If you are taking any other medicines (including those not prescribed by your doctor).
- If you are pregnant and nursing babies.
- If you are having active liver disease or increased blood transaminase level.
- If you are having type I diabetes mellitus.
- If you are premenopausal anovulatory (no ovulation before menopause) women.
- If you are having eyes disorders.

### Taking other medicines

You should tell your doctor if you are taking any medicine as it may interact with your Axcel Rosiglitazone Tablet:

- CYP2C8 inhibitors (gemfibrozil) or inducers (rifampicin).

It may still be all right for you to take Axcel Rosiglitazone Tablet and your doctor will be able to decide what is suitable for you.

## HOW TO USE AXCEL ROSIGLITAZONE TABLET

### How much to use

The management of antidiabetic therapy should be individualized. The usual starting dose of Rosiglitazone is 4mg administered either as a single dose once daily or in divided doses twice daily.

Dose adjustment is needed when co-administered with other drugs:

Monotherapy:

For patient who respond inadequately following 12 weeks of treatment, the dose may be increased to 8mg administered as a single dose once daily or in divided doses twice daily.

Combination therapy with metformin, sulfonylurea or metformin and sulfonylurea:

Dose may increase to 8mg/day following 8 weeks of therapy. Administered as a single dose in the morning, or divided and administered in the morning and evening.

### When to use it

Your doctor will decide when it is appropriate for you to use Axcel Rosiglitazone Tablet according to the type of condition you have. This tablet can be taken with or without food.

### How long to use it

Continue taking Axcel Rosiglitazone Tablet for as long as doctor recommends.

### If you forget to use it

Consult your 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)

- In the event of overdose, appropriate supportive treatment should be initiated as dictated by the patient's clinical status.

It is advisable for you to contact and inform your doctor if you did take Axcel Rosiglitazone Tablet too much.

## WHILE YOU ARE USING IT

### 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

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are taking Axcel Rosiglitazone Tablet.

- Tell your doctor immediately if you become pregnant while talking 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 Axcel Rosiglitazone Tablet to anyone else, even if they have the same symptoms or condition as you.

## Things to be careful of

- Not recommended in paediatric population.
- Discontinue administration of Rosiglitazone when signs and symptoms of heart failure develop. Please consult your doctor for advice immediately.

## SIDE EFFECTS

Like all medicines, Axcel Rosiglitazone Tablet can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following common side effects have been reported:

### Common side effects

- Low blood sugar.
- Headache.
- Weight gain.
- Low red blood cells.
- Dizziness.
- Gastrointestinal disturbances.
- Muscle cramps.
- Shortness of breath.
- Tingling.
- Itch
- High level cholesterol in blood

### Very rare side effects

- Serious allergic reaction which causes swelling of the face and throat
- Urticaria (itching and rash resulting from allergic).

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 [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers -> Reporting).

## STORAGE AND DISPOSAL OF AXCEL ROSIGLITAZONE TABLET

### Storage

Keep Axcel Rosiglitazone Tablet out of reach of children.

Store below 30°C. Keep container well closed and protect from light.

### Disposal

Do not use Axcel Rosiglitazone Tablet after the expiry date which is stated on the carton.

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

Axcel Rosiglitazone-4mg Tablet is triangle shape, marked with "KOTRA" on one side, film-coated orange tablets.

Axcel Rosiglitazone-8mg Tablet is triangle shape, marked with "KOTRA" on one side, film-coated red brown tablets.

### Ingredients

#### Active Ingredient:

Rosiglitazone Maleate equivalent to Rosiglitazone.

#### Inactive Ingredients:

Avicel, Lactose Monohydrate, Hydroxypropyl Methylcellulose E5, Sodium Starch Glycolate, Magnesium Stearate, Opadry Pink, Purified Water.

### MAL Numbers

Axcel Rosiglitazone-4mg Tablet

MAL12055025A

Axcel Rosiglitazone-8mg Tablet

MAL12055026A

## MANUFACTURER AND PRODUCT REGISTRATION HOLDER

KOTRA PHARMA (M) SDN BHD  
No. 1, 2 & 3, Jalan TTC 12,  
Cheng Industrial Estate,  
75250 Melaka, Malaysia.

## DATE OF REVISION

28/05/2014