

## Avandia™ Tablets

Rosiglitazone 4mg and 8mg tablets

Consumer Medicine Information

---

### What is in this leaflet?

---

Please read this leaflet carefully before you take *Avandia* tablets.

This leaflet answers some common questions about *Avandia* tablets. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking *Avandia* tablets against the benefits this medicine is expected to have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

Keep this leaflet with the medicine. You may need to read it again.

---

### What *Avandia* is used for

---

*Avandia* tablets contain the active ingredient rosiglitazone.

This medicine belongs to a group of drugs that lower high blood sugar levels (anti-diabetic) called *thiazolidinediones*.

It is used in the treatment of Type 2 diabetes (non-insulin dependent diabetes mellitus).

It may be used in patients inadequately controlled by diet and exercise and in combination with sulphonylureas and

metformin (other blood glucose lowering agents) or insulin to improve blood glucose levels.

**Diabetes** is a condition in which the body does not produce enough insulin or else the body tissues are not able to use the insulin present. This leads to hyperglycaemia (too much sugar in the blood). Symptoms include excessive thirst, the passing of a greatly increased amount of urine, increase in appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell.

---

### Before you take your *Avandia* tablet

---

#### When you must not take *Avandia*

Do not take *Avandia* tablets if you have ever had an allergic reaction to rosiglitazone or any of the ingredients listed at the end of this leaflet.

Do not take *Avandia* tablets if you have heart failure requiring treatment. If you have heart failure talk to your doctor.

Do not take *Avandia* tablets if you have severe liver problems.

Do not take *Avandia* tablets if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.

Your doctor will discuss the risks and benefits of using *Avandia* tablets if you are

pregnant or breastfeeding.

- Do not take *Avandia* tablets after the expiry date (EXP) printed on the pack.

If you use the tablets after the expiry date has passed, they may not work as well.

- Do not take *Avandia* tablets if the packaging is torn or shows signs of tampering.

If you're not sure whether you should be taking *Avandia* tablets, talk to your doctor.

### What you must do

You must tell your doctor if:

- you have liver disease
- you have a heart condition or you have heart failure or at risk of having heart failure
- you are already taking insulin
- you are already taking nitrates for existing heart disease
- you are taking other anti-diabetic medications. The dose of these other medications may need to be decreased to reduce any risk of hypoglycaemia (low sugar levels in the blood).
- you have breathing difficulties
- you have a history of swelling of legs and feet

- you have been treated for a condition called *polycystic ovary syndrome* because as a consequence of improving your diabetic symptoms, it may also resume ovulation in premenopausal women and put patients at risk of pregnancy.
- Have had any menstrual irregularity
- you are taking any other medicines, including those you buy from a supermarket, pharmacy or health food shop.
- you have visual disorders

Broken bones, usually in the hand, upper arm or foot, have been seen with rosiglitazone use in women. Talk to your doctor for advice on how to keep your bones healthy.

Heart problems such as angina or heart attack have been reported in patients who were on insulin and *Avandia* was added or in patients taking nitrates for known heart disease.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when using *Avandia* tablets while taking other medicines.

### Use in children

There is no information on the use of *Avandia* tablets in children who are under 18 years of age and therefore use in this age group is not recommended.

---

### **How to take *Avandia* tablets**

---

Take your medicine as your doctor has told you. The label on the pack will tell you how many tablets to take and how often you should take them. If you do not understand what you should do, ask your doctor or pharmacist.

*Avandia* tablets can be taken with or without food.

### How much to take

#### **Treatment of diabetes mellitus**

##### **Adults**

The dosage of *Avandia* is different for each patient.

The recommended starting dose for *Avandia* is 4mg/day. If you require a higher dose, after 6 to 8 weeks of therapy the dose can be increased to 8mg/day. *Avandia* can be given once or twice a day.

If you take too much (overdose) immediately telephone your doctor or Poisons Information Centre (0800 POISON) or 0800 764 766) for advice, if you think you or anyone else may have taken too many *Avandia* tablets, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

---

### **While you are taking *Avandia* tablets**

---

#### ***Things you must do***

Tell your doctor or pharmacist that you are taking *Avandia* if you are about to be started on any new medicines.

Tell your doctor if you become pregnant or are trying to become pregnant.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think it was not effective and change your treatment unnecessarily.

#### ***Things you must not do***

Do not change the dose of your *Avandia* tablets without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

#### ***Things to be careful of***

*Avandia* tablets generally do not cause any problems with your ability to drive a car or operate machinery. *Avandia* does not cause drowsiness or sedation.

#### ***Side-Effects***

**Check with your doctor as soon as possible if you have any problems while taking *Avandia* tablets, even if you do not think the problems are connected with the medicine or are not listed.**

Like other medicines, *Avandia* tablets can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be

serious and need medical attention.

*Avandia* may increase the risk of 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

A few patients have experienced the following side effects whilst taking *Avandia*:

- Fluid retention
- cough, chest infection
- weight gain
- a small reduction in red blood cell count (anaemia) and white blood cell count
- low blood sugar levels (hypoglycaemia). This occurs more often when *Avandia* is taken with sulphonylureas or insulin.
- heart failure or fluid in the lungs (pulmonary oedema)
- heart problems such as angina or heart attack
- Headache
- visual disorders
- Broken bones, usually in the hand, upper arm or foot.

*Avandia* may increase your total cholesterol level slightly. Total cholesterol is made up of 'good cholesterol' (HDLc) and 'bad cholesterol' (LDLc) and it is the balance of these that is more important than the total level. *Avandia* does not affect the balance of good and bad cholesterol. If you

have any concerns about your cholesterol levels you should speak to your doctor.

If you think you are having an allergic reaction to *Avandia* tablets, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital. Symptoms of an allergic reaction usually include some or all of the following:

- wheezing.
- swelling of the lips/mouth.
- difficulty in breathing.
- hay fever.
- lumpy rash ("hives").
- fainting.

This is not the complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

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

#### **After taking Avandia tablets**

#### **Storage**

**Keep this medicine where young children cannot reach it.**

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

**Keep *Avandia* tablets in the pack in a cool, dry place where it stays below**

**30°C and out of direct light.**

**Do not store them, or any other medicine, in a bathroom or near a sink.**

**Do not leave them in the car or on window sills.**

Heat, light and dampness can destroy some medicines.

#### **Disposal**

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

#### **Product description**

##### **What Avandia tablets look like**

*Avandia* tablets are pentagonal shaped. The tablets are 4mg (orange) and 8mg (red-brown)

##### **Ingredients**

Each *Avandia* tablet contains the active ingredients rosiglitazone 4mg or 8mg.

*Avandia* tablets also contain inactive ingredients: Sodium starch glycollate, hydroxypropyl methylcellulose, microcrystalline cellulose, lactose monohydrate magnesium stearate. *Avandia* tablets are film coated. The film coat contains: hydroxypropyl methylcellulose 6cP, titanium, iron oxide yellow E172, iron oxide red E172, purified talc.

##### **Manufacturer**

Your *Avandia* tablets are supplied by:

GlaxoSmithKline NZ  
Quay Tower  
Cnr Albert and Customs St  
Private Bag 106600  
Downtown, Auckland

Ph: (09) 367 2900  
Fax: (09) 367 2910

***Further information***

Pharmaceutical companies are not in a position to give people individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

**Do not throw this leaflet away. You may need to read it again.**

Prepared January 2008  
Version 1.0

The information provided applies only to Avandia™ tablets™. Avandia is a trademark of the GlaxoSmithKline Group of Companies

This leaflet is copyrighted to GlaxoSmithKline and may be reproduced but not altered in any way.