

AVANDIA[®] TABLETS

Rosiglitazone

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take AVANDIA.

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

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

Please read this leaflet before you start taking AVANDIA. If you are helping someone else take AVANDIA, please read this leaflet before you give the first dose.

All medicines have risks and benefits. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the expected benefits of you taking AVANDIA against the risks this medicine could 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 is AVANDIA used for?

The name of your medicine is AVANDIA. It is also known as rosiglitazone.

AVANDIA belongs to a group of medicines called glitazones.

AVANDIA is used to treat patients with type 2 diabetes mellitus. This is also called non-insulin dependent

diabetes (NIDDM) or maturity onset diabetes.

Type 2 diabetes mellitus is a condition in which your body does not make enough insulin or where the insulin that your body produces does not work as well as it should. Insulin is a natural body chemical that helps the body's cells use the sugar from the blood and so stops your blood sugar levels from rising too high.

High blood sugar levels can cause damage to the body's cells.

AVANDIA acts by making your body more sensitive to insulin. It therefore helps your body make better use of the insulin it produces and thus helps to restore your blood sugar towards a normal level.

Your doctor may have prescribed AVANDIA for another reason.

AVANDIA can be used alone (when diet and exercise is not enough to treat your diabetes) or together with other anti-diabetic medicines.

There is no evidence that AVANDIA is addictive.

Before you take AVANDIA

Do not take AVANDIA if:

- you have heart failure or have had heart failure in the past.
- you are being treated for angina or having a heart attack.
- you have ever had an allergic reaction to AVANDIA or any of the ingredients listed in the Ingredients section of this leaflet. Signs of an allergic or

'anaphylactic' reaction may include itchy skin rash (hives), shortness of breath, difficulty breathing, wheezing, swelling of the face, tongue or other parts of the body or fainting.

- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Tell your doctor if:

You must tell your doctor if:

- you are breastfeeding, pregnant or trying to become pregnant. Your doctor will decide if this medicine is suitable for you.
- you have heart failure or have had heart failure in the past.
- you have breathing difficulties.
- you have a history of swelling or pain of legs and feet.
- you have a problem with your liver. The medicine may remain in your body longer than usual.
- you have visual disorders.
- you are taking insulin.
- you are taking nitrates for existing heart disease because heart problems such as angina and heart attack have been reported.
- 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 polycystic ovary syndrome. Due to the way your

medicine works there may be an increased risk of pregnancy.

- you are allergic to foods, dyes, preservatives or any other medicines.
- you are taking any other medicines, including medicines you buy without a prescription.
- you have problems with your kidneys.

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

AVANDIA only works in the presence of the body's own insulin therefore it should not be used in patients with type 1 (or insulin dependent) diabetes mellitus.

How do I take AVANDIA?

Follow your doctor's instructions about how and when to take your tablets; otherwise you will not fully benefit from your medicine.

How much to take:

Take AVANDIA as directed by your doctor or pharmacist.

The amount of AVANDIA people take can be different, and this depends on your condition. Your doctor will prescribe the best dose for you.

The usual starting dose of AVANDIA 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.

How to take AVANDIA:

Your AVANDIA tablets should be swallowed with a glass of water. They may be taken with or after a

meal or on an empty stomach. It is best to take the tablets at the same time each day.

If you are following a diabetic weight control diet you should continue with this while you are taking AVANDIA.

How long to take AVANDIA for:

Diabetes is a condition that requires long term treatment and regular assessment by your doctor. Once you have started taking medication, you will normally need to keep taking it for the rest of your life.

If you feel the effect of your medicine is too weak or too strong do not change the dose yourself, but ask your doctor.

Your doctor may prescribe AVANDIA in combination with other anti-diabetic medicines. Read the leaflets for these medicines too.

Do not stop taking AVANDIA, or change the dose without first checking with your doctor.

Use in children:

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

What do I do if I take too much AVANDIA? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much AVANDIA, even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor, pharmacist or nearest hospital. Show them the package containing the tablets.

If you forget to take AVANDIA:

Take your tablet as soon as you remember. Do not take any more than the usual dose. Take your next dose at the usual time.

While you are taking AVANDIA

Things you must do:

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

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Check with your doctor, pharmacist or dentist before taking any other medicines. This includes medicines that you buy without a prescription as well as prescribed medicines.

Things you must not do:

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

Do not use AVANDIA to treat any other complaints unless your doctor says to.

Things to be careful of:

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

What are the side-effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking AVANDIA, even if the problem is not listed below.

Like other medicines, AVANDIA 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 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

A few patients have experienced the following side-effects whilst taking AVANDIA:

- heart failure or fluid in the lungs (pulmonary oedema)
- heart problems such as angina or heart attack
- localised swelling (oedema)
- a small increase in weight
- low sugar levels in the blood (hypoglycaemia). This occurs more often when AVANDIA is taken with sulfonylureas.
- a small reduction in red blood cell count (anaemia) and white blood cell count
- broken bones, usually in the hand, upper arm or foot.
- an increase in appetite
- constipation

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.

Tell your doctor immediately if you notice any of the following:

- itchy skin rash (hives), shortness of breath, difficulty breathing, wheezing, swelling of the face, tongue or other parts of the body

or fainting. These could be symptoms of an allergic or 'anaphylactic' reaction.

- chest pain
- itching, rash
- dark urine or pale stools
- yellowing of the skin or eyes (jaundice)
- severe stomach cramps
- nausea or vomiting
- loss of weight
- tiredness
- shortness of breath
- swelling or pain of legs and feet
- rapid increase in weight
- visual disorders

These may be symptoms of rare but serious side effects and require urgent medical attention.

This is not a 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 or pharmacist if you notice any side effects from your medicine which are not mentioned here.

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

How do I store AVANDIA?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Do not leave in a car, on a window sill or in the bathroom.

Do not use after the expiry date stated on the pack has passed.

Store the tablets in the original package.

Keep your tablets in a place where the temperature stays below 30°C.

If your doctor stops your medicine, do not keep any leftover tablets

unless your doctor tells you to. Return any unused tablets to your pharmacist who will discard them safely.

Product description

What AVANDIA looks like:

AVANDIA is supplied to you as film-coated pentagonal shaped Tiltab[®] tablets in the following pack sizes:

4mg: 7, 28 tablets

8mg: 28 tablets

They are marked 'GSK' on one side and on the other is a number corresponding to the strength of the tablet. Each tablet strength is a different colour. Thus:

- '4' for the 4 mg Tiltab[®] tablet (orange)
- '8' for the 8 mg Tiltab[®] tablet (red-brown)

Ingredients

AVANDIA contains the active ingredient rosiglitazone.

AVANDIA also contains the following inactive ingredients: Sodium starch glycollate, hypromellose, cellulose microcrystalline, lactose, magnesium stearate, titanium dioxide, macrogol 3000, purified talc, lactose, glycerol triacetate, iron oxide yellow (CI77492) and iron oxide red (CI774911).

Patients who are intolerant to lactose should note that each AVANDIA tablet also contains a small amount of lactose.

Supplier:

Your AVANDIA is supplied by:
GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street,
Abbotsford, Victoria 3067
Australia.

Where to go for further information:

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

The information provided applies only to: AVANDIA®.

AVANDIA® and Tiltab® are registered trade marks of the GlaxoSmithKline group of companies.

AVANDIA 4 mg tablets: AUST R 70965

AVANDIA 8 mg tablets: AUST R 70966

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