

AVANDAMET TABLETS

Rosiglitazone (as maleate) and Metformin hydrochloride

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take AVANDAMET. If you are helping someone else to take AVANDAMET, please read this leaflet carefully before you give the first dose.

This leaflet answers some common questions about AVANDAMET. 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. 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 AVANDAMET 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 AVANDAMET used for?

AVANDAMET 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.

AVANDAMET contains two active ingredients; namely rosiglitazone (as maleate), which belongs to a group of medicines called glitazones, and metformin hydrochloride which belongs to a group of medicines called biguanides.

AVANDAMET 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.

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

Your doctor may have prescribed AVANDAMET for another reason.

There is no evidence that AVANDAMET is addictive.

Before you take AVANDAMET

Do not take if:

You must not take AVANDAMET if:

- you have ever had an allergic reaction to rosiglitazone, metformin or any of the ingredients listed toward the end of this leaflet (See "Ingredients"). 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.

- 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 juvenile diabetes mellitus that is uncomplicated and well regulated on insulin; diabetes mellitus which is regulated by diet alone; acute complications of diabetes mellitus such as metabolic acidosis, coma, infection, gangrene, or during or immediately following surgery where insulin is essential.
- you have kidney failure or reduced kidney function (e.g. if you are elderly).
- you have any conditions that may be associated with tissue hypoxia (where the tissue is deprived of oxygen) (e.g. gangrene, circulatory shock, acute significant blood loss); pulmonary embolism; severe liver failure; pancreatitis; excessive alcohol intake or the use of diuretics. This is due to the risk of lactic acidosis (an increased amount of lactic acid in the blood).
- 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.
- 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.
- 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. In particular, medicines that can affect the amount of sugar in your blood if you take them with AVANDAMET such as gemfibrozil, rifampicin, cimetidine and medicines that may change the amount of metformin in your blood, (especially if you have reduced kidney function) such as verapamil, rifampicin, cimetidine, dolutegravir, ranolazine, trimethoprim, vandetanib, isavuconazole, crizotinib, olaparib.
- you have kidney failure or may have reduced kidney function (e.g. if you are elderly).

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.

AVANDAMET 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.

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

How do I take AVANDAMET?

How much to take:

Take AVANDAMET as directed by your doctor or pharmacist.

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

Do not take more tablets than your doctor has recommended.

How to take it:

Your AVANDAMET tablets should be swallowed with a glass of water. They may be taken with or after a meal or on an empty stomach.

However, taking your tablets with or just after food will lessen the chance of a stomach upset.

It is best to take the tablets at the same time each day.

How long to take it 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 stop taking AVANDAMET or change the dose yourself, but ask your doctor.

Your doctor may prescribe AVANDAMET in combination with other anti-diabetic medicines.

Read the leaflets for these medicines too.

Use in children:

There is no information available on the use of AVANDAMET 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? (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 AVANDAMET, 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.

While you are taking AVANDAMET

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.

If you forget to take AVANDAMET, 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.

When taking AVANDAMET do not take any additional medicine containing metformin, either as a single or combination dose. Seek advice from your doctor or pharmacist.

Things you must not do:

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

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

Do not skip meals while taking AVANDAMET.

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

Things to be careful of:

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

If you have to be alert, for example when driving, be especially careful not to let your blood glucose levels fall too low.

Excessive alcohol intake should be avoided while taking AVANDAMET as it can enhance the effect of this medicine and can also cause lactic acidosis (an increased amount of lactic acid in the blood).

If you are elderly, you may have reduced kidney function and your doctor may wish to adjust your dose.

If you have any concerns you should speak to your doctor. Do not stop taking AVANDAMET or change the dose without checking with your doctor first.

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 AVANDAMET, even if the problem is not listed below.

AVANDAMET 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

Like other medicines, AVANDAMET 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.

The most commonly reported side-effects are:

- 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).
- a small reduction in red blood cell count (anaemia) and white blood cell count.
- broken bones, usually in the hand, upper arm or foot.
- metallic taste in the mouth.
- an increase in appetite.
- constipation.

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

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

AVANDAMET 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. AVANDAMET 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 or go to the Emergency Department at the nearest hospital if you notice any of the following symptoms of lactic acidosis (high lactic acid in the blood):

- nausea, vomiting or stomach pain.
- difficulty in breathing.
- feeling weak, tired or generally unwell.
- unusual muscle pain.
- sleepiness.
- dizziness or light-headedness.
- shivering, feeling extremely cold.
- slow heart beat.

You may need urgent medical attention. Lactic acidosis with AVANDAMET is rare. The risk of lactic acidosis is higher in some patients, including the elderly, those taking doses of metformin greater than 2 g per day, those drinking excessive amounts of alcohol and those whose kidneys are not working properly.

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 AVANDAMET?

AVANDAMET tablets should be stored in a cool, dry place below 30°C.

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.

Keep AVANDAMET tablets in their blister pack until it is time to take them.

Return any unused or expired medicine to your pharmacist.

Product description

What AVANDAMET looks like:

AVANDAMET tablets are film-coated oval tablets, debossed with 'gsk' on one side, and the following debossing on the reverse side. The tablets are also distinguished by colour.

'2/500' - 2 mg rosiglitazone/500 mg metformin hydrochloride pale pink tablet

'4/500' - 4 mg rosiglitazone/500 mg metformin hydrochloride orange tablet

'2/1000' - 2 mg rosiglitazone/1000 mg metformin hydrochloride yellow tablet

'4/1000' - 4 mg rosiglitazone/1000 mg metformin hydrochloride pink tablet

Ingredients

AVANDAMET contains the active ingredients rosiglitazone (as maleate) and metformin hydrochloride.

AVANDAMET also contains sodium starch glycollate, hypromellose, microcrystalline cellulose, povidone, lactose, magnesium stearate, titanium

dioxide, macrogol 400, iron oxide yellow and iron oxide red.

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

Supplier:

Your AVANDAMET 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. You may also be able to find general information about your disease and its treatment from patient information groups and product specific organisations e.g. Diabetes Australia.

This leaflet was prepared on 30 May 2019.

The information provided applies only to: AVANDAMET.

AVANDAMET:

2 mg/500 mg - AUST R 114516

4 mg/500 mg - AUST R 114517

2 mg/1000 mg - AUST R 115430

4 mg/1000 mg - AUST R 115459

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