

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Diovan.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will 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 Diovan is used for

Diovan belongs to a group of medicines called angiotensin II receptor antagonists (AIIRAs).

Hypertension

Diovan is used to control high blood pressure, also called hypertension. Everyone has blood pressure. This pressure helps get your blood around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have it is to have your blood pressure checked regularly.

High blood pressure increases the workload of the heart and blood vessels. If it continues for a long time, it can damage the blood vessels in the brain, heart and kidneys. This can lead to stroke, heart failure or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure reduces the chance of these disorders happening.

Heart Failure

Diovan is used to treat heart failure. Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops. Diovan helps the heart to function better and relieves some of the symptoms of heart failure.

Heart Attack

Diovan is also used to treat people after they have had a heart attack

(myocardial infarction) to reduce the risk of further heart damage and reduce further heart problems.

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 purpose.

There is not enough information to recommend the use of Diovan in children (below 18 years of age).

This medicine is only available with a doctor's prescription. It is not habit-forming.

Before you take Diovan

When you must not take it

Do not take Diovan if you have ever had an allergic reaction after taking:

- valsartan (the active ingredient in Diovan)
- any of the other ingredients listed at the end of this leaflet

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Diovan if you are pregnant or intend to become pregnant.

Diovan is not recommended for use in pregnancy. Like other similar medicines, it could affect your unborn baby.

Do not take Diovan if you have liver disease caused by a blockage

in the bile duct or any other severe liver disease.

Diovan is not recommended if you have these conditions.

Do not take Diovan if you are also taking other blood pressure lowering medicines containing aliskiren and have type 2 diabetes.

Do not take Diovan after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

In that case, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you have any of the following health problems/ medical conditions:

- heart disease or high blood pressure that is being treated with large doses of diuretics (also called water or fluid tablets), or being treated with beta-blockers, aliskiren and/or ACE-inhibitors
- high blood pressure due to narrowing of the arteries in the kidney
- any other kidney problems or are having dialysis
- milder forms of liver disease
- swelling, mainly of the face and throat, while taking other medicines (including an ACE inhibitor or aliskiren)
- you have recently had severe vomiting or diarrhoea
- you are severely limiting your salt intake
- primary hyperaldosteronism (Conn's syndrome), a hormone disorder causing fluid retention
- obstructed blood flow through the heart from narrowing of valves (stenosis) or enlarged septum of the heart (HOCM)

Your doctor may want to take special precautions if you have any of the above conditions.

Tell your doctor if you are breast-feeding. Ask your doctor about the

risks and benefits of taking Diovan in this case.

It is not known if valsartan, the active ingredient of Diovan, passes into the breast milk and could affect your baby.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Your doctor will want to know if you are prone to allergies.

If you have not told your doctor about any of these things, tell them before you take Diovan.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Other medicines may be affected by Diovan or they may affect how well Diovan works. You may need to take different amounts of your medicines or you may need to take different medicines.

These medicines include:

- beta-blockers, which are medicines used to treat hypertension or other heart conditions
- ACE-inhibitors or aliskiren, which are also medicines used to treat hypertension or other heart conditions
- some diuretics (water or fluid pills)
- potassium supplements (e.g. Slow-K®) or other drugs that may increase potassium levels
- salt substitutes containing potassium
- lithium (a medicine used to treat some types of psychiatric illness)
- some antibiotics (rifamycins), anti-rejection drugs (cyclosporin), antiretrovirals (ritonavir) which may increase the effect of Diovan
- anti-inflammatory medicines such as Celebrex, Voltaren and Indocid

(NSAIDs) or Selective Cyclooxygenase-2 Inhibitors (Cox-2 Inhibitors).

- trimethoprim containing medicines

Your doctor may also check your kidney function.

Your doctor and pharmacist have a more complete list of medicines to be careful of while taking Diovan.

How to take Diovan

Follow carefully all directions given to you by your doctor and pharmacist.

These instructions may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

For hypertension, the usual dose is one 80 mg tablet once a day. If your blood pressure is still too high after 4 weeks, your doctor may increase the dose to 160 mg once a day, or from 160 mg to 320 mg once a day. If your blood pressure is still too high, your doctor may add a different type of blood pressure lowering medicine.

For heart failure the usual starting dose is 40 mg twice daily. Your doctor may increase the dose gradually up to one 160 mg tablet twice daily.

Following a heart attack, treatment is generally started at a dose of 20 mg (half a 40 mg tablet) twice daily. Your doctor may increase the dose gradually up to 160 mg twice daily.

When to take it

When you take the first tablet from the pack of Diovan, take the one marked with the correct day of the week (e.g. if it is Wednesday, take the tablet marked Wednesday).

Diovan comes in a calendar pack with the days of the week marked on it to help you remember to take your tablet each day.

Take it at the same time each day.

This also helps you remember to take it, especially if you take it as part of your usual routine (e.g. at breakfast time).

How to take it

Swallow the tablet with a full glass of water. Always take it in the same way in relation to food.

It does not matter if you take it after food or on an empty stomach, as long as you take it the same way each day.

If your stomach is upset after taking Diovan, always take it after a meal (e.g. breakfast).

How long to take it

Take this medicine until your doctor tells you to stop even if you feel quite well.

It will take at least 4 weeks for this medicine to have its full effect. After that, it will be continued for as long as your doctor thinks it is needed.

If you forget to take it

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

Otherwise, take the dose as soon as you remember and then go back to taking it as you would normally.

Do not take a double dose to make up for the one that you missed.

This may increase the chance of you getting unwanted side effects.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone number: 13 11 26) for advice, or go to Accident and

Emergency at your nearest hospital if you think that you or anyone else may have taken too much Diovan. Do this even if there are no signs of discomfort or poisoning.

Keep the telephone numbers for these places handy.

Too much Diovan may make you feel dizzy, lightheaded or faint. You may experience rapid, shallow breathing or cold, clammy skin. Your heartbeat may be faster than usual. This is because your blood pressure is too low.

While you are taking Diovan

Things you must do

If you become pregnant while taking Diovan, tell your doctor immediately.

You should not take this medicine while you are pregnant.

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

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Be sure to keep all of your doctor's appointments so that your progress can be checked. Do this even if you feel well.

It is important to keep track of your progress. Your doctor will want to check your blood pressure and your kidney and liver function from time to time.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Diovan.

Tell any other doctor, dentist or pharmacist who treats you that you are taking Diovan.

Things you must not do

Do not use Diovan to treat any other complaints unless your doctor says you can.

Do not give this medicine to anyone else, even if their condition seems to be similar to yours.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking Diovan until you know how it affects you.

This medicine can cause tiredness, sleepiness or dizziness in some people. If you have these symptoms, do not drive or do anything else that could be dangerous.

If this medicine makes you feel dizzy or light-headed, be careful when getting up from a sitting or lying position.

Dizziness can usually be prevented by getting up slowly and flexing leg muscles and toes to get the blood flowing. When getting out of bed, dangle your legs over the side for a minute or two before standing up.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Diovan, even if you do not think it is connected with the medicine.

All medicines can have side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of these side effects and they worry you:

- headache
- dizziness, spinning sensation (vertigo)
- sleepiness, tiredness or weakness
- diarrhoea, constipation or wind
- nausea (feeling sick), vomiting, loss of appetite, stomach pains or indigestion
- dry cough, sore throat or hoarse voice
- blistering skin
- runny nose or congested sinuses
- pain in the back or joints
- muscle pain or cramps
- difficulty sleeping
- feeling anxious
- tingling or numbness in the hands or feet
- problems with sexual function

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; fever, shortness of breath, wheezing or troubled breathing
- feeling of fast or irregular heart beat (pounding, racing, skipping beats)
- chest pain
- shortness of breath not caused by exercise, with swelling of legs or feet
- tiredness or lack of energy, being short of breath when exercising, dizziness and looking pale
- constant "flu-like" symptoms such as chills, fever, sore throat, aching joints, sores in mouth, swollen glands
- severe dizziness or fainting
- liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine

The above side effects may be serious. You may need urgent medical attention.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using Diovan

Storage

- Keep your tablets in the original container until it is time to take them.
- Store them in a cool dry place (room temperature).
- Do not store Diovan or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines. Diovan will keep well if it is cool and dry.

Keep the medicines where children cannot reach them.

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 Diovan, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Diovan tablets are supplied in blister packs of 28.

Diovan 40 mg tablets are oval and yellow marked with "DO" on one side and "NVR" on the other.

Diovan 80 mg tablets are round and pale red with a "D" and "V" marked

on one side of the tablet and "NVR" on the other.

Diovan 160 mg tablets are oval shaped, and grey-orange in colour. They have the letters "DX/DX" marked on one side of the tablet and "NVR" on the other.

Diovan 320 mg tablets are oval shaped, and grey-violet in colour. They have the letters "DXL" marked on one side of the tablet and "NVR" on the other.

Ingredients

Diovan tablets contain 40 mg, 80 mg, 160 mg or 320 mg of valsartan as the active ingredient.

The tablets contain the following non active ingredients:

- cellulose microcrystalline
- crospovidone
- silica - colloidal anhydrous
- magnesium stearate
- hypromellose
- titanium dioxide
- macrogol 8000
- iron oxide red CI77491
- iron oxide yellow CI77492

The 40 mg, 160 mg and 320 mg tablets also contain:

- iron oxide black CI77499

Diovan tablets and capsules do not contain glucose, lactose, sucrose, saccharin, gluten, tartrazine or other azo dyes.

Sponsor

Diovan is supplied in Australia by:
NOVARTIS Pharmaceuticals

Australia Pty Limited

ABN 18 004 244 160

54 Waterloo Road

North Ryde NSW 2113

Telephone: 1 800 671 203

®= Registered Trademark

This leaflet was prepared in February 2015.

Australian Registration Numbers:

Diovan 40 mg tabs AUST R 93165

Diovan 80 mg tabs AUST R 80868

Diovan 160 mg tabs AUST R 80871

Diovan 320 mg tabs AUST R 123357

For internal use only:

(CMI dvn140220c is based on PI
dvn140220i)