

DIOVAN®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Diovan?

Diovan contains the active ingredient Valsartan. Diovan is used to control high blood pressure, also called hypertension.

It is also used to treat heart failure. For more information, see Section [1. Why am I using Diovan?](#) in the full CMI.

2. What should I know before I use Diovan?

Do not use if you have ever had an allergic reaction to Diovan or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Diovan?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Diovan and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Diovan?

- 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 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.

More instructions can be found in Section [4. How do I use Diovan?](#) in the full CMI.

5. What should I know while using Diovan?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Diovan.• If you become pregnant while taking Diovan, tell your doctor immediately.• Tell your doctor, if for any reason, you have not taken your medicine exactly as prescribed.
Things you should not do	<ul style="list-style-type: none">• Do not stop 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.
Driving or using machines	<ul style="list-style-type: none">• 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.
Looking after your medicine	<ul style="list-style-type: none"> • Keep the tablets in the original packet and foils until it is time to take them. • Store the tablets in a cool, dark and dry place at room temperature.

For more information, see Section [5. What should I know while using Diovan?](#) in the full CMI.

6. Are there any side effects?

Common side effects: headache, dizziness, tiredness, diarrhoea, constipation or wind, muscle or joint pain or tenderness, abdominal pain, nausea, vomiting, dry cough, sore throat, hoarse voice, runny or blocked nose, blistering skin, difficulty sleeping, feeling anxious, tingling or numbness in the hands or feet, problems with sexual function.

Serious side effects: swelling of hands, feet or limbs, feeling of fast or irregular heartbeat, shortness of breath, tiredness, chest pain, severe dizziness, liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine, constant "flu-like" symptoms.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

DIOVAN®

Active ingredient(s): *Valsartan*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Diovan. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Diovan.**

Where to find information in this leaflet:

- [1. Why am I using Diovan?](#)
- [2. What should I know before I use Diovan?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Diovan?](#)
- [5. What should I know while using Diovan?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Diovan?

Diovan contains the active ingredient Valsartan. Diovan belongs to a group of medicines called angiotensin II receptor antagonists (AIIAs).

Diovan is used to control high blood pressure, which is also called hypertension.

Diovan is also used to treat heart failure, by helping the heart to function better and relieve some of the symptoms. Heart failure is where the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body.

Diovan is also used to treat people after they have a heart attack, to reduce the risk of further heart damage and reduce further heart problems.

2. What should I know before I use Diovan?

Warnings

Do not use Diovan if:

- you are allergic to Valsartan, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

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.

- you are pregnant, or intending to become pregnant.
- you have impaired liver function caused by a blockage in the bile duct or any other severe liver problems.

- you are also taking other blood pressure lowering medications containing Aliskiren and have type 2 diabetes.

Check with your doctor if you have any other medical conditions such as:

- 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 you are having dialysis
- liver problems
- 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
- very low sodium levels and/or low blood pressure
- primary hyperaldosteronism (Conn's syndrome), a hormone disorder causing accumulation of fluid in the body.
- 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 allergic to any other medicines, foods, dyes or preservatives.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not recommended to breast feed while taking Diovan as it is not known if valsartan, the active ingredient of Diovan, passes into the breast milk.

3. What if I am taking other medicines?

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

Some medicines may interfere with Diovan and affect how it 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®), salt substitutes containing potassium, or other drugs that may increase potassium levels (heparin, trimethoprim)
- 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) used to treat arthritis

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Diovan.

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

4. How do I use Diovan?

Follow carefully all directions given to you by your doctor and pharmacist. These instructions may differ from the information contained in the leaflet.

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

How much to take

How much Diovan to take will depend on what you are taking it for:

- 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 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.

Follow the instructions provided and use Diovan until your doctor tells you to stop.

When to take Diovan

- Following a heart attack, your first dose of Diovan will be started as early as 12 hours after your heart attack.
- 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 (i.e. at breakfast time).

If you forget to use Diovan

Diovan should be used regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose 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 dose 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 Diovan

If you think that you have used too much Diovan, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Taking 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.

5. What should I know while using Diovan?

Things you should do

- If you become pregnant while taking Diovan, tell your doctor immediately. You should not be taking 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 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.

Call your doctor straight away 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 parts of the body; fever, shortness of breath, wheezing or troubled breathing.

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Diovan affects you.

Diovan may 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.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep your tablets in the original container until it is time to take them.

Store it in a cool dry place (room temperature) away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- 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 it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering. In that case, return it to your pharmacist for disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gut or Gastrointestinal related</p> <ul style="list-style-type: none">• diarrhoea, constipation or wind• nausea (feeling sick), vomiting, loss of appetite, stomach pains or indigestion <p>Throat related</p> <ul style="list-style-type: none">• dry cough, sore throat or hoarse voice• runny or blocked nose <p>Skin related</p> <ul style="list-style-type: none">• blistering skin <p>General</p>	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● headache ● dizziness, spinning sensation, especially when getting up from a sitting or lying position ● sleepiness, tiredness or weakness ● 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. 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● Feeling of fast or irregular heart beat (pounding, racing, skipping beats) ● Chest pain ● Shortness of breath not caused by exercise, with swelling of legs and 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 ● Bleeding or bruising more easily than normal ● 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 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. Some side effects can only be found when your doctor does tests to check your progress. Diovan can affect certain blood and liver function tests.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

Diovan is only available with a doctor's prescription.

What Diovan contains

Active ingredient (main ingredient)	Valsartan
Other ingredients (inactive ingredients)	<p>The tablets contain the following non active ingredients:</p> <ul style="list-style-type: none">• microcrystalline cellulose• crospovidone• colloidal anhydrous silica• magnesium stearate• hypromellose• titanium dioxide• macrogol 8000• red iron oxide• yellow iron oxide <p>The 40 mg, 160 mg and 320 mg tablets also contain:</p> <ul style="list-style-type: none">• black iron oxide
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

What Diovan looks like

Diovan tablets are supplied in blister packs of 28.

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

Diovan 80 mg tablets: 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: 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: oval shaped, and grey-violet in colour. They have the letters "DC/DC" marked on one side of the tablet and "NVR" on the other.

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

Who distributes Diovan

Diovan is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

(ABN 18 004 244 160)

54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1 800 671 203

Website: www.novartis.com.au

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