

Consumer Medicine Information (CMI) summary

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

1. Why am I taking DILART?

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

For more information, see Section [1. Why am I taking DILART?](#) in the full CMI.

2. What should I know before I take DILART?

Do not take if you have ever had an allergic reaction to valsartan 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 take DILART?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DILART 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 take DILART?

- 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 take DILART?](#) in the full CMI.

5. What should I know while taking DILART?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using DILART.• If you become pregnant while taking DILART, 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 take DILART to treat any other complaints unless your doctor says you can.• Do not give DILART to anyone else, even if their condition seems to be similar to yours
Driving or using machines	<ul style="list-style-type: none">• DILART 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 taking DILART?](#) 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.

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking DILART?

DILART contains the active ingredient valsartan. DILART belongs to a group of medicines called angiotensin II receptor antagonists (AIIRAs).

DILART is used to control high blood pressure, which is 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.

DILART is also used to treat heart failure.

DILART helps 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. Heart failure is not the same as heart attack and does not mean that the heart stops.

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

2. What should I know before I take DILART?

Warnings

Do not take DILART if:

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

Some of the 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

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

- you are pregnant or intend 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
- expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

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 DILART if you are pregnant or intend to become pregnant.

DILART 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 DILART as it is not known if valsartan, the active ingredient of DILART, passes into the breast milk.

Use in children

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

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 DILART 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, salt substitute 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 DILART
- anti-inflammatory medicines such as celecoxib, diclofenac and indometacin (NSAIDs) or Selective cyclooxygenase-2 Inhibitors (Cox-2 inhibitors) used to treat arthritis
- trimethoprim containing medicines.

Your doctor may also check your kidney function.

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

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

4. How do I take DILART?

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 DILART 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 DILART until your doctor tells you to stop.

When to take DILART

- Following a heart attack, your first dose of DILART will be started as early as 12 hours after your heart attack.
- When you take the first tablet from the pack of DILART, take the one marked with the correct day of the week (e.g. if it is Wednesday, take the tablet marked Wednesday).
- DILART 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).

How to take DILART

- 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 DILART, always take it after a meal (e.g. breakfast).

How long to take DILART for

- 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 is needed

If you forget to take DILART

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 DILART

If you think that you or anyone else has taken too much DILART, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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.

Too much DILART 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 taking DILART?

Things you should do

- If you become pregnant while taking DILART, 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.

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking DILART.
- Tell any other doctor, dentist or pharmacist who treats you that you are taking DILART.

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 DILART 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 DILART affects you.

DILART 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

- Keep your tablets in the original container until it is time to take them.
- Store at room temperature.

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

Store it in a cool dry place 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. DILART 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 metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

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

Do not take 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.

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

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

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 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 bleeding or bruising more easily than normal severe dizziness or fainting 	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.

Serious side effects	What to do
<ul style="list-style-type: none"> 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. DILART 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

This medicine is only available with a doctor's prescription.

What DILART contains

Active ingredient (main ingredient)	valsartan
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> microcrystalline cellulose crospovidone povidone croscarmellose sodium colloidal anhydrous silica magnesium stearate The 40 mg tablet contains: Opadry Complete Film Coating System 08F520002 Yellow (ID: 144620) The 80 mg tablet contains: Opadry Complete Film Coating System 08F540003 Pink (ID: 146273) The 160 mg tablet contains: Opadry Complete Film Coating System 08F520000 Yellow (ID: 146272) The 320 mg tablet contains: Opadry Complete Film Coating System 08F565001 Brown (ID: 146276)

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

What DILART looks like

DILART 40 mg tablets are yellow, oval shaped, biconvex, film coated tablets debossed with "VN" and "1" on either side of the score line on one side and "M" on the other side (AUST R 167425).

DILART 80 mg tablets are pale red, round, biconvex, bevelled edge, film- coated tablets having a score line on one side and debossed with "M" over "VN 2" on other side (AUST R 167427).

DILART 160 mg tablets are beige, oval-shaped, biconvex, bevelled edge, film-coated tablets debossed with "M" to the left of the score on one side and "VN 3" on the other side (AUST R 167426).

DILART 320 mg tablets are dark grey, oval shaped, biconvex, film coated tablets debossed with "VN 4" on one side and "M" on the other side (AUST R 167421).

DILART tablets are supplied in blister packs of 28.

Who distributes DILART

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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