DILART® HCT

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> 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 HCT?

DILART HCT contains the active ingredient valsartan and hydrochlorothiazide. DILART HCT is used to control high blood pressure also known as hypertension.

For more information, see Section <u>1. Why am I taking</u> <u>DILART HCT?</u> in the full CMI.

2. What should I know before I take DILART HCT?

Do not take if you have ever had an allergic reaction to DILART HCT 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 HCT? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with DILART HCT 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 HCT?

- Swallow the tablet with a full glass of water. Always take DILART HCT the same way in relation to food.
- If your stomach is upset after taking DILART HCT, always take it after a meal (e.g. breakfast).

More instructions can be found in Section <u>4. How do I take DILART HCT?</u> in the full CMI.

5. What should I know while taking DILART HCT?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking DILART HCT.
- If you become pregnant while taking DILART

	 HCT, tell your doctor immediately. Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. If you are going to have surgery, tell your doctor and anaesthetist that you are taking DILART HCT.
Things you should not do	 Do not take DILART HCT 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 HCT affects you.
Drinking alcohol	 Tell your doctor if you drink alcohol.
Looking after your medicine	 Keep DILART HCT in the original container until it is time to take it.

 Store it below 25°C (room temperature).

For more information, see Section <u>5. What should I know while taking DILART HCT?</u> in the full CMI.

6. Are there any side effects?

Less serious side effects: headache; dizziness, blurred vision; sleepiness; pain in the back or joints; runny or bleeding nose or congested sinuses; dry cough, sore throat or hoarse voice; dry mouth; nausea vomiting, loss of appetite, stomach upset or indigestion; back pain, muscle pain, cramps or joint pain; tingling or numbness in hands or feet; blistering skin; symptoms of sunburn; difficulty sleeping; feeling anxious or sad; problems with sexual function; pain when passing urine, frequent urge to urinate; hair loss; facial pain. Serious side effects: signs of allergy; fast or irregular heartbeat; chest pains; flu-like symptoms; decrease in vision or pain in the eyes; liver disease; unusual bleeding or bruising under the skin; pain in the stomach; tiredness or lack of energy; severe dizziness or fainting; severe shortness of breath, fever, weakness and confusion.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> effects? in the full CMI.

DILART® HCT

Active ingredient(s): valsartan and hydrochlorothiazide

Consumer Medicine Information (CMI)

This leaflet provides important information about taking DILART HCT. 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 HCT.

Where to find information in this leaflet:

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

1. Why am I taking DILART HCT?

DILART HCT contains the active ingredient valsartan and hydrochlorothiazide. These medicines reduce blood pressure in two different ways.

Valsartan blocks the effect of angiotensin II, which is a substance in the body that tightens blood vessels and makes your blood pressure rise. When the effect of angiotensin II is blocked, your blood vessels relax and your blood pressure goes down.

Hydrochlorothiazide helps reduce the amount of excess fluid in the body by increasing the amount of urine produced. This helps lower your blood pressure.

DILART HCT is used to control high blood pressure, also called hypertension.

Everybody has blood pressure. This pressure helps get your blood all 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 (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

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.

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.

DILART HCT is not addictive.

2. What should I know before I take DILART HCT?

Warnings

Do not take DILART HCT if:

• you have ever had an allergic reaction after taking:

- valsartan or hydrochlorothiazide (the active ingredients in DILART HCT) or sulfonamide derived medicines (such as some antibiotics eg. trimethoprim and sulfamethoxazole)
- any of the other ingredients listed at the end of this leaflet
 Symptoms of an allergic reaction may include:
- o 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 have:

- severe kidney or liver disease including biliary cirrhosis
- cholestasis, which is reduced or stopped bile flow
- anuria, which is a condition where you are unable to urinate
- high uric acid levels in the blood, which may cause gout

 low level of potassium or sodium, or high level of calcium in your blood

Check with your doctor if you are unsure if you have any of the above conditions.

- you are also taking other blood pressure lowering medicines containing aliskiren and have type 2 diabetes
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.
 In that case, return it to your pharmacist.

Check with your doctor if you:

- have or have had any of the following health problems/ medical conditions:
 - kidney problems
 - liver problems
 - systemic lupus erythematosus, a disease affecting the skin, joints and kidneys
 - heart problems, including obstructed blood flow from narrowing of valves (stenosis) or enlarged septum (HOCM)
 - o high cholesterol levels
 - diabetes
 - swelling, mainly of the face and throat, while taking other medicines (including an ACE inhibitor or aliskiren)
 - primary hyperaldosteronism (Conn's syndrome), a hormone disorder causing fluid retention

- passing less urine than is normal for you or difficulty passing urine
- recent excessive vomiting or diarrhoea
- salt restricted diet
- If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past.

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

- take any medicines for any other condition
- 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 DILART HCT.

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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

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

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

Tell your doctor if you are breastfeeding a baby. Ask your doctor about the risks and benefits of taking DILART HCT in this case.

Hydrochlorothiazide is known to pass into the breast milk, however it is not known if valsartan passes into the breast milk. Therefore, DILART HCT is not recommended if you are breastfeeding.

Children

There is not enough information to recommend the use of DILART HCT in children.

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 HCT and affect how it works. These include:

- medicines used to treat high blood pressure and some other heart conditions including fluid tablets or diuretic medicines, ACE-inhibitors, aliskiren and beta blockers
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- tablets, preparations or supplements which contain potassium

- some antibiotics (rifamycins), anti-rejection drugs (ciclosporin), antiretrovirals (ritonavir) which may increase the effect of valsartan
- medicines or supplements containing calcium
- vitamin D
- other medicines that raise blood pressure
- medicines used to relax muscles before or during surgery
- steroid medicines such as cortisone, prednisone and ACTH
- lithium, antidepressants, antipsychotics, medicines used to treat mood swings and some types of depression
- medicines used to treat heart problems
- cyclophosphamide monohydrate or methotrexate
- penicillin
- amphotericin B (amphotericin), a medicine used to treat fungal infections
- insulin and tablets used to treat diabetes
- medicines used to treat gout
- ciclosporin
- carbamazepine (a drug used to treat epilepsy, bipolar disorders, neuralgia and other conditions)
- medicines used to lower cholesterol (e.g. colestyramine)
- amantadine, a medicine used to treat Parkinson's disease or to prevent influenza

- anticholinergic medicines, which are used to treat Parkinson's disease, relieve stomach cramps, spasms and prevent travel sickness
- carbenoxolone, a medicine used to treat stomach ulcers
- antiarrhythmics and digitalis glycosides, medicines used to treat irregular heart beats
- tetracycline, a medicine used to treat some infections
- alcohol
- sleeping tablets
- radioactive iodine, used as a medical tracer or diagnosis
- trimethoprim containing medicines

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

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 HCT.

4. How do I take DILART HCT?

How much to take

 The usual dose is 80/12.5 mg, 160/12.5 mg or 320/12.5 mg once a day. If your blood pressure is still too high after 4 weeks, your doctor may increase the dose to 160/25 mg or 320/25 mg once a day.

When to take DILART HCT

 When you take the first dose from the pack of DILART HCT, take the one marked with the correct day of the week (e.g. if it is Wednesday, take the dose from the section of the foil marked Wednesday).

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

 Take your DILART HCT dose 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). This medicine will keep working for the whole 24 hours until the next dose is due.

How to take DILART HCT

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

It does not matter if you take DILART HCT 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 HCT, 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.

People who have high blood pressure often feel well and do not notice any signs of this problem.

It will take at least 4 weeks for this medicine to have its full effect. After that, it can be continued for as long as needed to control your blood pressure.

If you forget to take DILART HCT

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 dose you missed.

This may increase the chance of side effects.

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

If you take too much DILART HCT

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

You should immediately:

phone the Poisons Information Centre

(by calling 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.

Keep the telephone numbers for these places handy.

Too much DILART HCT may make you feel dizzy, light-headed 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 HCT?

Things you should do

- 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.

People with high blood pressure often do not notice any signs of this problem. But it is important to keep track of your progress. Your doctor will want to check your blood pressure regularly to make sure the medicine is working. Your doctor will also check your kidney and liver function from time to time to prevent unwanted side effects.

- If you are going to have surgery, tell your doctor and anaesthetist that you are taking DILART HCT.
 DILART HCT may affect some medicines you receive during surgery.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking DILART HCT.

Call your doctor straight away if you:

• become pregnant while taking DILART HCT You should not take this medicine while you are pregnant.

Remind any doctor, dentist or pharmacist you visit that you are taking DILART HCT.

Things you should not do

- Do not take DILART HCT 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

 If this medicine makes you feel dizzy or lightheaded, 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.

 When you are outdoors, wear protective clothing and use at least a 15+ sunscreen. Do not use a sunlamp.

This medicine may cause your skin to be much more sensitive to sunlight than it normally is. Exposure to sunlight may cause a skin rash, itching, redness or severe sunburn. If your skin does appear to be burning, tell your doctor.

 Some medicines may require additional subheading(s) relevant to monitoring the condition and actions to be taken while on the medicine e.g. bleeding risk with antiplatelets / hypoglycaemia and what to do.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how DILART HCT 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- keep DILART HCT in the original container until it is time to take it.
- store it below 25°C (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 HCT 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.

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.

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

Less serious side effects

Less serious side effects	What to do
 headache dizziness, spinning sensation, blurred vision sleepiness, tiredness or weakness 	Speak to your doctor if you have any of these less serious side effects and they worry you.
 pain in the back or joints runny or bleeding nose or congested sinuses 	
dry cough, sore throat or hoarse voicedry mouth	
 diarrhoea, constipation or wind 	
 nausea (feeling sick), vomiting, loss of appetite, stomach upset or indigestion 	
 back pain, muscle pain, muscle tenderness or 	

Less serious side effects	What to do
weakness, cramps or joint pain	
 tingling or numbness in hands or feet 	
blistering skin	
 symptoms of sunburn which happens more quickly than normal difficulty sleeping feeling anxious or sad 	
 dizziness on standing up, especially when getting up from a sitting or lying position problems with sexual 	
function	
 pain when passing urine, frequent urge to urinate 	
• hair loss	
• facial pain	

Serious side effects

Serious side effects	What to do
 signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing 	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.
 feeling of fast or irregular heartbeat (pounding, racing, skipping beats) 	
 chest pain 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 pain in the stomach, often accompanied by nausea and vomiting 	

Serious side effects What to do signs of a serious skin reaction such as painful red areas, large blisters, peeling of layers of skin, bleeding in the lips, eyes, mouth, nose or genitals. These signs may be accompanied by fever and chills, aching muscles and feeling generally unwell unusual bleeding or bruising under the skin severe dizziness or fainting passing less urine than normal liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes and dark coloured urine decrease in vision or pain in your eyes signs of acute respiratory distress such as severe shortness of breath, fever, weakness and confusion

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.

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 HCT contains

Active ingredient (main ingredient)	Valsartan and hydrochlorothiazide
Other ingredients (inactive ingredients)	colloidal anhydrous silicasodium lauryl sulfate

- crospovidone
- povidone
- magnesium stearate
- microcrystalline cellulose
- pregelatinised maize starch
- lactose monohydrate
- Opadry II complete film-coating system 03F84793 pink (ID: 107334) [80/12.5 tablets]
- Opadry II complete film-coating system 03B57310 brown (ID: 107338) [160/12.5 tablets]
- Opadry II complete film-coating system 03F86873 brown (ID: 107335) [160/25 tablets]
- Opadry II complete film-coating system 03F84782 pink (ID: 107336) [320/12.5 tablets]
- Opadry II complete film-coating system 03F82965 yellow (ID: 107337) [320/25 tablets]

Potential allergens Sugars as lactose

DILART HCT tablets contain 80 mg, 160 mg or 320 mg of valsartan and 12.5 mg or 25 mg of hydrochlorothiazide as the active ingredient.

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

What DILART HCT looks like

- DILART HCT 80/12.5 tablets are a peach, film-coated, oval, biconvex tablet debossed with VH 1 on one side of the tablet and M on other side (AUST R 187397).
- DILART HCT 160/12.5 tablets are a reddish, film-coated, oval, biconvex tablet debossed with VH 2 on one side of the tablet and M on other side (AUST R 187403).
- DILART HCT 160/25 tablets are a brown, film-coated, oval, biconvex tablet debossed with VH 3 on one side of the tablet and M on other side (AUST R 187400).
- DILART HCT 320/12.5 tablets are a pink, film-coated, oval, biconvex tablet debossed with VH 4 on one side of the tablet and M on other side (AUST R 187402).
- DILART HCT 320/25 tablets are a yellow, film-coated, oval, biconvex tablet debossed with VH 5 on one side of the tablet and M on other side (AUST R 187399).

Each blister pack contains 28 tablets.

Who distributes DILART HCT

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

This leaflet was prepared in December 2025.

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