

AMLODIPINE/VALSARTAN/HCT NOVARTIS®

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 AMLODIPINE/VALSARTAN/HCT NOVARTIS?

AMLODIPINE/VALSARTAN/HCT NOVARTIS contains the active ingredients Amlodipine Besilate, Valsartan and Hydrochlorothiazide. AMLODIPINE/VALSARTAN/HCT NOVARTIS is used to control high blood pressure, also called hypertension. For more information, see Section [1. Why am I using AMLODIPINE/VALSARTAN/HCT NOVARTIS?](#) in the full CMI.

2. What should I know before I use AMLODIPINE/VALSARTAN/HCT NOVARTIS?

Do not use if you have ever had an allergic reaction to AMLODIPINE/VALSARTAN/HCT NOVARTIS 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 AMLODIPINE/VALSARTAN/HCT NOVARTIS?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with AMLODIPINE/VALSARTAN/HCT NOVARTIS 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 AMLODIPINE/VALSARTAN/HCT NOVARTIS?

- The usual dose is one tablet a day. Your doctor will tell you how many tablets to take each day. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.
- Take this medicine until your doctor tells you to stop even if you feel quite well.

More instructions can be found in Section [4. How do I use AMLODIPINE/VALSARTAN/HCT NOVARTIS?](#) in the full CMI.

5. What should I know while using AMLODIPINE/VALSARTAN/HCT NOVARTIS?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using this medicine• If you become pregnant while taking this medicine, 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 AMLODIPINE/VALSARTAN/HCT NOVARTIS. AMLODIPINE/VALSARTAN/HCT NOVARTIS may affect some medicines you receive during surgery. |
| Things you should not do | <ul style="list-style-type: none">• Do not stop use this medicine 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 (30°C). |

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

6. Are there any side effects?

Common side effects: headache, persistent ringing in the ears, 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 or sad, tingling or numbness in the hands or feet, problems with sexual function, breast enlargement in men, unusual hair loss or thinning.

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.

AMLODIPINE/VALSARTAN/HCT NOVARTIS®

Active ingredient(s): Amlodipine besilate/Valsartan/hydrochlorothiazide

Consumer Medicine Information (CMI)

This leaflet provides important information about using AMLODIPINE/VALSARTAN/HCT NOVARTIS. 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 AMLODIPINE/VALSARTAN/HCT NOVARTIS.

Where to find information in this leaflet:

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

1. Why am I using AMLODIPINE/VALSARTAN/HCT NOVARTIS?

AMLODIPINE/VALSARTAN/HCT NOVARTIS contains the active ingredients, amlodipine besilate, valsartan and hydrochlorothiazide. AMLODIPINE/VALSARTAN/HCT NOVARTIS belongs to a group of medicines called antihypertensives. These medicines help treat high blood pressure. The ingredients in AMLODIPINE/VALSARTAN/HCT NOVARTIS reduce blood pressure in three 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.
- Amlodipine besilate blocks the movement of calcium into the cells of the heart and blood vessels. As a result, they relax blood vessels and increase the supply of blood and oxygen to the heart while reducing its workload.
- Hydrochlorothiazide helps reduce the amount of excess fluid in the body by increasing the amount of urine produced. This helps lower your blood pressure.

AMLODIPINE/VALSARTAN/HCT NOVARTIS is used to control high blood pressure, which is also called hypertension.

AMLODIPINE/VALSARTAN/HCT NOVARTIS is only used to treat high blood pressure in patients who already use and have success with the combination of valsartan, amlodipine besilate and hydrochlorothiazide individually.

AMLODIPINE/VALSARTAN/HCT NOVARTIS is used to substitute these three medicines into a single tablet.

2. What should I know before I use AMLODIPINE/VALSARTAN/HCT NOVARTIS?

Warnings

Do not use AMLODIPINE/VALSARTAN/HCT NOVARTIS if:

- you are allergic to valsartan, amlodipine besilate or hydrochlorothiazide; allergic to medicines belonging to a group of chemicals called dihydropyridines, used to treat blood pressure and other heart problems; allergic to medicines belonging to a group of chemicals called sulfonamide-derived (such as some antibiotics e.g. Bactrim trimethoprim and sulfamethoxazole) or any of the ingredients listed at the end of this leaflet.
- you are pregnant, or intending to become pregnant.
- you have severe kidney disease or are having dialysis
- you have liver problem caused by a blockage in the bile duct or any other severe liver problems.
- you have cholestasis, which is reduced or stopped bile flow
- you have anuria, which is a condition where you are unable to urinate
- you have high uric acid levels in the blood, which may cause gout
- you have a low level of potassium or sodium, or high level of calcium in your blood
- you are also taking other blood pressure lowering medications containing aliskiren and have type 2 diabetes.
- it is 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.

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

- kidney problems or received a kidney transplant
- liver problems
- systemic lupus erythematosus, a disease affecting the skin, joints and kidneys
- heart problems, including obstructed blood flow through the heart from narrowing of valves (stenosis) or an enlarged septum of the heart (HOCM)
- primary hyperaldosteronism (Conn's syndrome), a hormone disorder causing build-up of fluid in the body.
- swelling, mainly of the face and throat, while taking other medicines (including an ACE inhibitor or aliskiren)
- suffering from vomiting or diarrhoea

- passing less urine than is normal for you or difficulty passing urine
- a salt restricted diet
- skin cancer
- breathing or lung problems (including inflammation or fluid in the lungs) following the use of hydrochlorothiazide in the past.

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 AMLODIPINE/VALSARTAN/HCT NOVARTIS if you are pregnant or intend to become pregnant. AMLODIPINE/VALSARTAN/HCT NOVARTIS 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. Ask your doctor about the risks and benefits of taking AMLODIPINE/VALSARTAN/HCT NOVARTIS. Hydrochlorothiazide and amlodipine are known to pass into the breast milk. It is not known if valsartan, an active ingredient of AMLODIPINE/VALSARTAN/HCT NOVARTIS, passes into the breast milk and could affect your baby.

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 AMLODIPINE/VALSARTAN/HCT NOVARTIS 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:

- medicines used to treat high blood pressure and some other heart conditions including fluid tablets or diuretic medicines, ACE-inhibitors, aliskiren and beta blockers
- simvastatin (a medicine used to help lower cholesterol levels), since the dose may have to be reduced when taken with AMLODIPINE/VALSARTAN/HCT NOVARTIS
- intravenous dantrolene used to treat malignant hyperthermia
- some antibiotics (rifamycins), anti-rejection drugs (Cyclosporin), antiretrovirals (Ritonavir) which may increase the effect of valsartan
- potassium supplements, salt substitutes containing potassium, or other drugs that may increase potassium levels
- anti-inflammatory medicines such as Celebrex, Voltaren and Indocid (NSAIDs) or Selective Cyclooxygenase-2 Inhibitors (Cox-2 inhibitors)

- medicines or supplements containing calcium
- vitamin D
- 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
- cyclophosphamide or methotrexate
- penicillin
- amphotericin, a medicine used to treat fungal infections
- insulin and tablets used to treat diabetes
- medicines used to treat gout
- cyclosporine
- carbamazepine, an anticonvulsant and mood stabilising drug used primarily in the treatment of epilepsy and bipolar disorder
- digoxin or other digitalis glycosides (medicines used to treat heart problems)
- antiarrhythmics (medicines used to treat heart problems)
- medicines used for oesophageal ulceration and inflammation
- amantadine, and anti-Parkinson therapy also used to treat or prevent certain illnesses caused by viruses
- cytotoxic drugs used in cancer therapy
- medicine used to treat gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as aid to anaesthesia from a class called anticholinergic agents
- cholestyramine, colestipol, and other resins (medicines used mainly to treat high levels of lipids in the blood)
- pressor amines, such as noradrenaline (substances that raise blood pressure)
- barbiturates, narcotics (medicines with sleep-inducing properties) and alcohol.
- radioactive iodine, used as a medical tracer or diagnosis.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect AMLODIPINE/VALSARTAN/HCT NOVARTIS.

Your doctor or pharmacist have a more complete list of medicines to be careful of while taking AMLODIPINE/VALSARTAN/HCT NOVARTIS.

4. How do I use AMLODIPINE/VALSARTAN/HCT NOVARTIS?

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

- Your doctor will tell you how many tablets to take each day. The usual dose is one tablet a day.
- Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.
- 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.

When to take AMLODIPINE/VALSARTAN/HCT NOVARTIS

- 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 AMLODIPINE/VALSARTAN/HCT NOVARTIS

- Swallow the tablet with a full glass of water
- Always take AMLODIPINE/VALSARTAN/HCT NOVARTIS in the same way, with or without food.

You can take it with or without food but it will work best if you always take it in the same day everyday.

If you forget to take AMLODIPINE/VALSARTAN/HCT NOVARTIS

AMLODIPINE/VALSARTAN/HCT NOVARTIS 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 AMLODIPINE/VALSARTAN/HCT NOVARTIS (overdose)

If you think that you have used too much AMLODIPINE/VALSARTAN/HCT NOVARTIS, 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 AMLODIPINE/VALSARTAN/HCT NOVARTIS 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 AMLODIPINE/VALSARTAN/HCT NOVARTIS?

Things you should do

- If you become pregnant while taking AMLODIPINE/VALSARTAN/HCT NOVARTIS, 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.

People with high blood pressure often do not notice any signs of this problem. 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 going to have surgery, tell your doctor and anaesthetist that you are taking AMLODIPINE/VALSARTAN/HCT NOVARTIS. AMLODIPINE/VALSARTAN/HCT NOVARTIS 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 AMLODIPINE/VALSARTAN/HCT NOVARTIS.

Things to be careful of

- Avoid eating grapefruit or drinking grapefruit juice. Grapefruit juice can affect the metabolism of some medicines, including amlodipine.

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.

Remind any doctor, dentist or pharmacist you visit that you are using AMLODIPINE/VALSARTAN/HCT NOVARTIS.

Things you should not do

- Do not use AMLODIPINE/VALSARTAN/HCT NOVARTIS 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 AMLODIPINE/VALSARTAN/HCT NOVARTIS affects you.

AMLODIPINE/VALSARTAN/HCT NOVARTIS 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 below 30°C (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. AMLODIPINE/VALSARTAN/HCT NOVARTIS 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.

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 |
|---|---|
| <ul style="list-style-type: none"> • headache • buzzing, whistling, ringing or other persistent noise in the ears • dizziness, spinning sensation, changes in vision, uncoordinated movements • dizziness on standing up, especially when getting up from a sitting or lying position • sleepiness, tiredness, weakness or difficulty sleeping | <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"> • pain in the back or joints • muscle pain, muscle tenderness or weakness, cramps • runny nose or congested sinuses • dry cough, sore throat or hoarse voice • dry mouth • bleeding, tender or enlarged gums • stomach upset, pain, diarrhoea or constipation • nausea (feeling sick) or vomiting • tingling or numbness in hands or feet • rash, redness, blistering or peeling of skin, itching • excessive sweating • feeling anxious or sad • problems with sexual function • breast enlargement in men • unusual hair loss or thinning | |

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 and feet • tiredness or lack of energy, being short of breath when exercising, dizziness and looking pale • bleeding or bruising more easily • 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 | <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> |

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

AMLODIPINE/VALSARTAN/HCT NOVARTIS is only available with a doctor's prescription.

What AMLODIPINE/VALSARTAN/HCT NOVARTIS contains

| | |
|---|--|
| Active ingredient (main ingredient) | Amlodipine besilate, Valsartan, and Hydrochlorothiazide |
| Other ingredients (inactive ingredients) | The tablets contain the following non active ingredients: <ul style="list-style-type: none">• cellulose microcrystalline• crospovidone• silica - colloidal anhydrous• magnesium stearate• hypromellose• macrogol 4000• talc - purified• titanium dioxide• iron oxide yellow• iron oxide red |
| Potential allergens | None |

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

What AMLODIPINE/VALSARTAN/HCT NOVARTIS looks like

AMLODIPINE/VALSARTAN/HCT NOVARTIS 5/160/12.5 (5 mg amlodipine, 160 mg valsartan and 12.5 mg hydrochlorothiazide) tablets are white, ovaloid, biconvex with bevelled edge and imprinted with NVR on one side and VCL on the other. Packs of 7's and 28's.

AMLODIPINE/VALSARTAN/HCT NOVARTIS 10/160/12.5 (10 mg amlodipine, 160 mg valsartan and 12.5 mg hydrochlorothiazide) tablets are pale yellow, ovaloid, biconvex with bevelled edge and imprinted with NVR on one side and VDL on the other. Packs of 7's and 28's.

AMLODIPINE/VALSARTAN/HCT NOVARTIS 5/160/25 (5 mg amlodipine, 160 mg valsartan and 25 mg hydrochlorothiazide) tablets are yellow, ovaloid, biconvex with bevelled edge and imprinted with NVR on one side and VEL on the other. Packs of 7's and 28's.

AMLODIPINE/VALSARTAN/HCT NOVARTIS 10/160/25 (10 mg amlodipine, 160 mg valsartan and 25 mg hydrochlorothiazide) tablets are brown yellow, ovaloid, biconvex with bevelled edge and imprinted with NVR on one side and VHL on the other. Packs of 7's and 28's.

AMLODIPINE/VALSARTAN/HCT NOVARTIS 10/320/25 (10 mg amlodipine, 320 mg valsartan and 25 mg hydrochlorothiazide) tablets are brown yellow, ovaloid, biconvex with bevelled edge and imprinted with NVR on one side and VFL on the other. Packs of 7's and 28's.

AMLODIPINE/VALSARTAN/HCT NOVARTIS tablets are non-divisible and cannot be divided into equal doses.

Australian Registration Numbers:

AMLODIPINE/VALSARTAN/HCT NOVARTIS 5/160/12.5 (AUST R 158161)

AMLODIPINE/VALSARTAN/HCT NOVARTIS 5/160/25 (AUST R 158163)

AMLODIPINE/VALSARTAN/HCT NOVARTIS 10/160/12.5 (AUST R 158165)

AMLODIPINE/VALSARTAN/HCT NOVARTIS 10/160/25 (AUST R 158167)

AMLODIPINE/VALSARTAN/HCT NOVARTIS 10/320/25 (AUST R 158169)

Who distributes AMLODIPINE/VALSARTAN/HCT NOVARTIS

AMLODIPINE/VALSARTAN/HCT NOVARTIS 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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