

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 ALPHAPRESS?

ALPHAPRESS contains the active ingredient hydralazine hydrochloride. ALPHAPRESS is used to lower high blood pressure, also known as hypertension.

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

2. What should I know before I take ALPHAPRESS?

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

3. What if I am taking other medicines?

Some medicines may interfere with ALPHAPRESS 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 ALPHAPRESS?

- The usual starting dose is 25 mg twice a day. Your doctor may increase your dose depending on how you respond to this medicine.
- Swallow the tablets with a glass of water.

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

5. What should I know while taking ALPHAPRESS?

Things you should do	• Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine. • If you become pregnant while taking this medicine, tell your doctor immediately. • If you are going to have surgery, including dental surgery, tell your surgeon, anaesthetist or dentist that you are taking this medicine.
Things you should not do	• Do not take ALPHAPRESS to treat any other complaints unless your doctor tells you to. • Do not give your medicine to anyone else, even if they have the same condition as you. • Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how ALPHAPRESS affects you.
Drinking alcohol	• Be careful drinking alcohol while you are taking this medicine.
Looking after your medicine	• Store below 25°C. Protect from light. • Keep your tablets in the bottle until it is time to take them.

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

6. Are there any side effects?

Less serious side effects include: dizziness, headache, flushing, nausea, vomiting, diarrhoea, blocked nose, irregular heartbeat.

Serious side effects include: chest pain, allergy symptoms, skin rash, itching or hives, muscle aches, painful swollen joints, joint pain, fever and shortness of breath, swelling of the feet or legs due to fluid build-up or passing little urine or no urine.

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.

ALPHAPRESS™

Active ingredient(s): *hydralazine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ALPHAPRESS. **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 ALPHAPRESS.**

Where to find information in this leaflet:

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

1. Why am I taking ALPHAPRESS?

ALPHAPRESS contains the active ingredient **hydralazine hydrochloride**.

ALPHAPRESS is used to **lower high blood pressure, also known as hypertension**. It is normally used together with other medicines for high blood pressure.

This medicine works by widening the blood vessels so that blood passes through them more easily. This helps to lower blood pressure.

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 reason.

There is no evidence that ALPHAPRESS is addictive.

2. What should I know before I take ALPHAPRESS?

Warnings

Do not take ALPHAPRESS if:

- you are allergic to any medicine containing hydralazine hydrochloride or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin
- Always check the ingredients to make sure you can take this medicine.
- you have:
 - o systemic lupus erythematosus (SLE)

- o certain heart conditions such as heart failure, narrowing of the valves in the heart or swelling around the heart
 - o a very fast, irregular or pounding heartbeat
 - o a condition called dissecting aortic aneurysm where there is swelling and weakening of a large blood vessel
 - o thyrotoxicosis (an overactive thyroid gland)
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- take any medicines for any other condition
 - have allergies to any other medicines, foods, preservatives or dyes
 - have or have had any of the following medical conditions:
 - o heart failure, coronary heart disease such as angina or a recent heart attack, or any other heart problem
 - o stroke or any other problems with poor blood flow to the brain
 - o kidney problems
 - o liver problems
- Your doctor may want to take special care if you have any of these conditions.
- plan to have surgery.

If you have not told your doctor about any of the above, tell them before you start taking ALPHAPRESS.

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

Tell your doctor if you are pregnant or plan to become pregnant.

ALPHAPRESS may affect your developing baby if you take it during pregnancy.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding or wish to breastfeed.

The active ingredient in ALPHAPRESS passes into breast milk and there is a possibility that your baby may be affected.

Use in children

Do not give this medicine to children.

Safety and effectiveness in children have not been established.

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 ALPHAPRESS and affect how it works. These include:

- medicines used to treat high blood pressure or heart conditions such as beta-blockers (e.g. propranolol, metoprolol); ACE inhibitors and calcium channel blockers
- diuretics, also called fluid or water tablets
- monoamine oxidase inhibitors and tricyclic antidepressants, which are medicines used to treat depression
- medicines used to treat certain mental and emotional conditions such as schizophrenia
- adrenaline, a medicine used in emergency situations or to treat a severe allergic reaction

These medicines may be affected by ALPHAPRESS or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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

4. How do I take ALPHAPRESS?

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

They may differ from the information contained in this leaflet.

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

How much to take

- The usual starting dose is 25 mg twice a day.
- Your doctor may increase your dose depending on how you respond to this medicine.

When to take ALPHAPRESS

- Take your medicine at about the same time each day.
Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take ALPHAPRESS

- Swallow the tablets with a glass of water.

How long to take ALPHAPRESS for

- Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take ALPHAPRESS

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 it as soon as you remember, and then go back to taking your medicine 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 an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much ALPHAPRESS

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

You should immediately:

- phone the Poisons Information Centre (**by calling 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.

Symptoms of an overdose may include having a very fast or irregular heartbeat, chest pain, sweating, feeling sick, dizzy or faint.

5. What should I know while taking ALPHAPRESS?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ALPHAPRESS.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.
- If you are going to have surgery, including dental surgery, tell your surgeon, anaesthetist or dentist that you are taking this medicine.
- If you become pregnant while taking this medicine, tell your doctor immediately.
- Keep all of your doctor's appointments so that your progress can be checked.

You may need to have tests to check your blood and kidneys.

Things you should not do

- Do not take ALPHAPRESS to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of

- If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Driving or using machines

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

ALPHAPRESS may cause dizziness or light-headedness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness or light-headedness may be worse.

Looking after your medicine

- Store below 25°C. Protect from light.
- Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

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.

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?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ALPHAPRESS.

This medicine helps most people with high blood pressure, but it may have unwanted side effects in a few people.

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 the following lists of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
• dizziness • headache • flushing • nausea (feeling sick), vomiting • diarrhoea • blocked nose • fast, irregular or pounding heartbeat The above list includes the more common side effects of your medicine. These side effects generally go away with continued treatment.	Speak to your doctor or pharmacist if you have any of these less serious side effects.

Serious side effects

Serious side effects	What to do
• severe pain in the stomach with bloating, gut cramps and vomiting • nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine • tiredness, headaches, being short of breath when exercising, dizziness and looking pale • frequent signs of infection such as fever, severe chills, sore throat or mouth ulcers • bleeding or bruising more easily than normal • tingling or numbness of the hands or feet • agitation, anxiety, depression, hallucinations	Tell your doctor as soon as possible if you notice any of these serious side effects.
• chest pain • wheezing or shortness of breath • skin rash, itching or hives	Call your doctor straight away, or go

Serious side effects	What to do
- muscle aches, painful swollen joints - systemic lupus erythematosus (SLE)-like syndrome with symptoms such as joint pain, fever and skin rash - shortness of breath and swelling of the feet or legs due to fluid build-up - passing little urine or no urine	straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.

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 ALPHAPRESS contains

Active ingredient (main ingredient)	hydralazine hydrochloride 25 mg or 50 mg
Other ingredients (inactive ingredients)	- microcrystalline cellulose - pregelatinised maize starch - disodium edetate - sodium starch glycollate - colloidal anhydrous silica - purified talc - magnesium stearate - Opadry Pink OY-LS-34902 (ID 2948) [50 mg tablets only]
Potential allergens	- sugars as lactose (50 mg tablets only) - trace quantities of sulfites.

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

What ALPHAPRESS looks like

- ALPHAPRESS 25 mg** - 8 mm cream, flat bevelled edged tablet with a score mark on one side (AUST R 17575).
- ALPHAPRESS 50 mg** - 7 mm pink film coated normal convex tablet marked HE 50 on one side, G on reverse (AUST R 60380).

Each bottle contains 100 tablets.

Who distributes ALPHAPRESS

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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ALPHAPRESS™ is a Viatris company trade mark

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