

ALPHAPRESS

hydralazine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ALPHAPRESS. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ALPHAPRESS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ALPHAPRESS is used for

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 not enough information to recommend the use of this medicine in children.

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

There is no evidence that this medicine is addictive.

Before you take ALPHAPRESS

When you must not take it

Do not take ALPHAPRESS if you have an allergy to:

- any medicine containing hydralazine hydrochloride
- 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

Do not take ALPHAPRESS if you have:

- systemic lupus erythematosus (SLE)
- certain heart conditions such as heart failure, narrowing of the valves in the heart or swelling around the heart
- a very fast, irregular or pounding heart beat
- a condition called dissecting aortic aneurysm where there is swelling and weakening of a large blood vessel
- thyrotoxicosis (an overactive thyroid gland)

Do not take this medicine after the expiry date printed on the pack 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.

Do not give this medicine to children.

Safety and effectiveness in children have not been established.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- heart failure, coronary heart disease such as angina or a recent heart attack, or any other heart problem
- stroke or any other problems with poor blood flow to the brain
- kidney problems
- liver problems

Your doctor may want to take special care if you have any of these conditions.

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.

Tell your doctor if you plan to have surgery.

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

Taking other medicines

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

Some medicines and ALPHAPRESS may interfere with each other. 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.

How to 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.

How to take it

Swallow the tablets with a glass of water.

When to take it

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 long to take it

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 it

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 that 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 (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you

think that you or anyone else may have taken too much ALPHAPRESS.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are using ALPHAPRESS

Things you must 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 must 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

Be careful driving or operating machinery until you know how ALPHAPRESS affects you.

This medicine 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.

Be careful drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or light-headedness may be worse.

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.

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. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dizziness
- headache
- flushing
- nausea (feeling sick), vomiting

- diarrhoea
- blocked nose
- fast, irregular or pounding heart beat

The above list includes the more common side effects of your medicine. These side effects generally go away with continued treatment.

Tell your doctor as soon as possible if you notice any of the following:

- 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

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest pain
- wheezing or shortness of breath
- skin rash, itching or hives
- 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using ALPHAPRESS

Storage

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.

Keep your tablets in a cool dry place where the temperature stays below 25°C. Protect from light.

Do not store ALPHAPRESS or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ALPHAPRESS is available in 2 strengths:

- 25 mg - scored, cream coloured tablet
- 50 mg - pink tablet marked HE over 50 on one side and G on the other

Each bottle contains 100 tablets.

Ingredients

ALPHAPRESS contains either 25 mg or 50 mg of hydralazine hydrochloride as the active ingredient.

The tablets also contain the following inactive ingredients:

- microcrystalline cellulose
- pregelatinised maize starch
- disodium edetate
- sodium starch glycollate
- colloidal anhydrous silica
- purified talc
- magnesium stearate
- Opadry Pink OY-LS-34902 [50 mg strength only]

The 50 mg tablets also contain lactose and traces of sulfites.

The tablets are gluten free.

Manufacturer

ALPHAPRESS is made in Australia by:

Alphapharm Pty Limited

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

ALPHAPRESS 25 - AUST R 17575

ALPHAPRESS 50 - AUST R 60380

This leaflet was prepared in

September 2019.

alphapress_cmi\sep19/01