contains the active ingredient 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 benefits and risks. Your doctor has weighed the risks of you taking Alphapress against the benefits expected for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What Alphapress is used for

Alphapress is used to lower high blood pressure, also called hypertension. It is normally used together with other medicines for high blood pressure.

Alphapress works by widening 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 Alphapress has been prescribed for you.

Your doctor may have prescribed Alphapress for another reason.

Alphapress is not recommended for use in children, as its safety and effectiveness in children has not been established.

Alphapress is available only with a doctor's prescription.

There is no evidence that Alphapress is addictive.

Before you take Alphapress

When you must not take it Do not take Alphapress if you are allergic to medicines containing hydrologies on

to medicines containing hydralazine or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, wheezing or shortness of breath, muscle and joint pain.

Do not take Alphapress if you have:

- systemic lupus erythematosus (SLE)
 certain heart conditions such as heart failure, narrowing of the valves in the
- hardwing of the valves in the heart or swelling around the heart
 a very fast, irregular or pounding heart
- a very fast, fregular of pounding heard 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 Alphapress if the expiry date (**EXP**) **printed on the bottle has passed.** If you take this medicine after the expiry date, it may not work as well.

Do not take Alphapress if the packaging shows signs of tampering or the tablets do not look quite right.

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 are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant. Alphapress may affect your baby if taken during recordered. Your doctor will discuss

during pregnancy. Your doctor will discuss the risks and benefits of taking it during pregnancy.

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

Alphapress passes into breast milk. Your doctor will discuss the risks and benefits of taking Alphapress when breastfeeding.

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 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 if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Alphapress or may affect how well it works. These include:

- medicines used to treat high blood pressure or heart conditions such as beta-blockers (eg. 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.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take Alphapress

Follow all directions given to you by your doctor and 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.

How much to take

The dose varies from person to person.

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

Alphapress is not recommended for children. *How to take Alphapress*

Swallow the tablets with a glass of water. *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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

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

How long to take Alphapress for Keep taking Alphapress for as long as

your doctor recommends. To properly control your blood pressure,

Alphapress must be taken every day.

If you take too much Alphapress (overdose)

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

If you take too much Alphapress, you may have a very fast or irregular heart beat, chest pain, sweat, feel sick, dizzy or faint.

While you are taking Alphapress

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Alphapress.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Alphapress.

If you become pregnant while taking Alphapress, tell your doctor immediately. If you plan to have surgery, including

dental surgery, tell your doctor or dentist that you are taking Alphapress.

Visit your doctor regularly so they can check on your progress.

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

Things you must not do

Do not use Alphapress to treat any other conditions unless your doctor tells you to. Do not give Alphapress to anyone else, even if they have the same condition as you.

Things to be careful of

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

Alphapress may cause dizziness or lightheadedness in some people. If either of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Be careful getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

Be careful drinking alcohol while taking Alphapress.

Combining alcohol with Alphapress may make you more dizzy or lightheaded.

Side effects

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

Alphapress helps most people with high blood pressure, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

Tell your doctor 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 and milder side effects of your medicine. These side effects generally go away with continued treatment.

See your doctor immediately 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, which may require medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- 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 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 Alphapress 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.

Keep your tablets in a cool dry place where the temperature stays below $25^\circ C$

Do not store Alphapress or any other medicine in the bathroom or near a sink.

Do not leave Alphapress in the car or on

window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Alphapress, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Alphapress is available in 2 tablet strengths:

- Alphapress 25 scored, cream coloured tablet.
- Alphapress 50 pink tablet marked HE over 50 on one side and G on the other.
- Each bottle contains 100 tablets.

Ingredients

The active ingredient in Alphapress is hydralazine hydrochloride.

- Each Alphapress 25 tablet contains 25 mg of hydralazine hydrochloride.
- Each Alphapress 50 tablet contains 50 mg of hydralazine hydrochloride.

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 [Alphapress 50 only].
- The tablets are gluten free.

Manufacturer

Alphapress is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739) Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000 Phone: (02) 9298 3999 www.mylan.com.au Australian registration numbers: Alphapress 25 - AUST R 17575 Alphapress 50 - AUST R 60380 This leaflet was prepared on 28 November 2016.

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