

Applicant/PHCR: Pharmaceutical Contractors (Pty) Ltd
Product proprietary name: Hypace Tablets
Dosage form and strength: Each tablet contains 5 mg Enalapril Maleate

1.3 Specific requirements for different types of applications

1.3.2 PIL amendments/update

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

PROPRIETARY NAME AND DOSAGE FORM

HYPACE 5 mg Tablet (5 mg enalapril maleate)

Read all of this leaflet carefully before you start taking HYPACE

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor or your pharmacist.
- HYPACE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

- 1. What Hypace is and what it is used for**
- 2. What you need to know before you take Hypace**
- 3. How to take Hypace**
- 4. Possible side effects**
- 5. How to store Hypace**
- 6. Contents of the pack and other information**

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1. What Hypace is and what it is used for

HYPACE is a medication that belongs to the group of medicines called angiotensin converting enzyme inhibitors, (ACE inhibitors).

Your doctor has prescribed HYPACE to treat your hypertension (high blood pressure) or heart failure (weakening of heart function).

HYPACE is also used for the prevention of symptomatic heart failure in patients with decreased heart function. HYPACE works by widening your blood vessels to make it easier for the heart to pump blood to all parts of your body.

2. What you need to know before you take Hypace

Do **not** take HYPACE if you:

- Are allergic to enalapril maleate or any of the other ingredients of

HYPACE (see “**WHAT HYPACE CONTAINS**”)

- Have previously been treated with a medication in the same group of medicines as HYPACE (ACE Inhibitors) or angiotensin receptor blockers (ARBs) and have had allergic reactions with swelling of the face, lips, tongue, and/or throat with difficulty in swallowing or breathing.

You should not take HYPACE if you have had these types of reactions without a known cause, or if you have been diagnosed with hereditary or idiopathic angio-oedema

- If you have hypertrophic obstructive cardiomyopathy, a heart disorder in which the walls of the ventricles (lower heart chambers)

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thicken (hypertrophy) and become stiff and the thickened muscle blocks the flow of blood out of the heart.

- If you have severe kidney disease.
- If you have narrowing of the blood vessels to both kidneys or to a single kidney.
- If you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of the heart) and the aorta (the main artery leading away from the heart).
- If you are taking diuretics (water pills) that cause your body to retain potassium such as spironolactone, triamterene and amiloride.
- Porphyria
- Lithium therapy: Using at the same time with HYPACE may lead to toxic blood concentrations of lithium
- Are pregnant and breastfeeding (see **Pregnancy and**

Breastfeeding)

If you are not sure whether you should start taking

HYPACE, contact your doctor.

Take special care with HYPACE

Tell your doctor about any medical problems you have or have had,

and about any allergies.

Tell your doctor if you have a heart condition, are undergoing dialysis or are being treated with diuretics (water tablets) or if you have recently

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suffered from excessive vomiting or diarrhoea. Also tell your doctor if you are on a salt-restricted diet, are taking potassium supplements, potassium-sparing agents or potassium-containing salt substitutes, have diabetes or any kidney problems, as these may lead to increased levels of potassium in the blood which can be serious. In these cases, your doctor may need to adjust the dosage of HYPACE or monitor your blood level of potassium. If you have diabetes and are taking oral antidiabetic medicines or insulin, you should closely monitor for low blood glucose levels, especially during the first month of treatment with HYPACE.

Tell your doctor if you have ever had an allergic reaction with swelling of the face, lips, tongue, and/or throat with difficulty in swallowing or breathing. Tell your doctor if you suffer from low blood pressure (you may notice this as faintness or dizziness, especially when standing). Before surgery and anaesthesia (even at the dentist's office), tell the doctor or dentist that you are taking HYPACE as there may be a sudden fall in blood pressure associated with anaesthesia.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby while taking HYPACE, please consult your doctor, pharmacist or other health care professional for advice.

Use in pregnancy

- Pregnant women should not use HYPACE as it can cause birth defects

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- Angiotensin-converting enzyme inhibitors (ACE inhibitors), including

HYPACE, can cause injury and death to the developing baby when taken during

the second and third trimesters of pregnancy

- If you are pregnant or intend to become pregnant, you must tell your

doctor before starting therapy with

HYPACE so that another treatment may be considered.

Use in breastfeeding

HYPACE is secreted in human milk in very small amounts. If you are breastfeeding or intend to breastfeed, consult your doctor.

Driving and using machinery

Individual responses to medication may vary. Certain side effects that have been reported with HYPACE may affect some patients' ability to drive or operate machinery (see **POSSIBLE SIDE EFFECTS**).

Important information about some of the ingredients of HYPACE

Hypace 5 mg contains lactose monohydrate

Patients with a rare hereditary conditions of lactose or galactose intolerance should not take Hypace 5 mg.

Taking other medicines with HYPACE

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If you are taking other medicines on a regular basis including complementary or traditional medicines, the use of HYPACE with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

In general, HYPACE can be taken with other medicines. However, it is important to tell your doctor about other medicines that you are taking, including those obtained without a prescription, as some medicines may affect each other's action.

For prescribing the correct dose of HYPACE, it is especially important for your doctor to know whether you are taking other medicines to reduce blood pressure, diuretics (water tablets), medicines containing potassium (including dietary salt substitutes), drugs for diabetes (including oral antidiabetic medicines and insulin), lithium (a medicine used to treat a certain kind of depression), certain pain and arthritis medicines including gold therapy, or fluoroquinolones.

3. How to take Hypace

Do not share medicines prescribed for you with any other person.

HYPACE may be taken with or between meals. Most people take

HYPACE tablets with a drink of water.

Your doctor will decide on the appropriate dose of HYPACE, depending on your condition and whether you are taking other medicines.

Always take HYPACE exactly as your doctor has instructed you.

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You should check with your doctor or pharmacist if you are unsure.

It is very important to continue taking HYPACE for as long as your doctor prescribes it. Do not take more tablets than the prescribed dosage. If you have the impression that the effect of HYPACE is too strong or too weak, talk to your doctor or pharmacist.

High Blood Pressure

For most patients, the usual recommended starting dose is 10 to 20 mg in tablet formulation taken once a day.

Some patients may need a lower starting dose. The usual long term dose is a 20 mg tablet taken once a day.

Heart Failure

The usual recommended starting dose is a 2,5 mg tablet taken once a day.

Your doctor will increase this amount step by step until the dose that is right for you has been achieved. The usual long term

dose is a 20 mg tablet per day taken in one or two doses.

Be especially careful when you take your first dose or if your dose

is increased. Let your doctor know immediately if you feel any light

headedness or dizziness.

If you take more HYPACE than you should: In the event of over

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dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. The most likely symptom would be a feeling of light-headedness or dizziness due to a sudden or excessive drop in blood pressure.

If you forget to take HYPACE: You should take HYPACE as prescribed.

However, if you miss a dose, do not take an extra dose.

Just resume your usual schedule.

4. Possible side effects

HYPACE can have side effects.

Not all side effects reported for HYPACE are included in this leaflet.

Should your general health worsen while taking HYPACE, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking HYPACE and tell your

doctor immediately or go to the casualty

department at your nearest hospital:

- If you develop swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing
- If you experience swelling of the hands, feet or ankles
- If you develop hives.

These are all very serious side effects. If you have them, you

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may have had a serious allergic reaction to HYPACE. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist promptly about any of these or any other unusual symptoms:

The following are frequent side effects:

Headache, dizziness or light-headedness due to a drop in blood pressure when standing up quickly, fainting, cough, nausea, diarrhoea, rash, weakness, tiredness

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>

5. How to store Hypace

HOW LONG SHOULD I KEEP MY MEDICINE?

Do not use this medicine after the month and year following

EXPIRES/VERVAL on the container.

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HOW SHOULD I STORE HYPACE?

Store in a dry place at or below 25 °C. Protect from light.

Keep all medicines out of reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or the sewerage system

(e.g. toilets).

6. Contents of the pack and other information

WHAT HYPACE CONTAINS

HYPACE (enalapril maleate,) is a tablet.

HYPACE tablets contain 5 mg of enalapril maleate as the active ingredient.

Other ingredients: Lactose Monohydrate, Microcrystalline Cell PH102

Talc Purified, Silicone Dioxide Coll Anhydrous

Croscarmellose Sodium

Packs of 28,56 or 200 tablets in securitainers and 28 or 56 tablets in blisters.

How Hypace looks like

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HYPACE 5 is a white to off-white, round, scored, flat bevelled tablet.

REGISTRATION NUMBERS

HYPACE 5: 33/7.1.3/0452

THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Pharmaceutical Contractors (PTY) Ltd

44 Monteer Road

Isando

1601

DATE OF LAST REVISION OF TEXT

To be determined