PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

BINDACE 2 mg (Tablet)

BINDACE 4 mg (Tablet)

BINDACE 8 mg (Tablet)

Perindopril tert-butylamine

Read all of this leaflet carefully before you start taking BINDACE

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or pharmacist

BINDACE 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 BINDACE CONTAINS

The active substance is perindopril.

BINDACE 2 mg: Each uncoated tablet contains perindopril tert-butylamine 2 mg.

The other ingredients are lactose, silica hydrophobic colloidal anhydrous, cellulose microcrystalline and magnesium stearate.

BINDACE 4 mg: Each uncoated tablet contains perindopril tert-butylamine 4 mg.

The other ingredients are lactose, silica hydrophobic colloidal anhydrous, cellulose microcrystalline and magnesium stearate.

BINDACE 8 mg: Each uncoated tablet contains perindopril tert-butylamine 8 mg.

The other ingredients are lactose, silica hydrophobic colloidal anhydrous, cellulose microcrystalline and magnesium stearate.

WHAT BINDACE IS USED FOR

Perindopril belongs to a class of medications called angiotensin-converting enzyme (ACE) inhibitors. It works by decreasing certain chemicals that tighten the blood vessels, so blood flows more smoothly and the heart can pump blood more efficiently.

BINDACE is used to treat high blood pressure and is also used to treat congestive heart failure (a condition where the heart is unable to pump enough blood to meet the body's needs).

3. BEFORE YOU TAKE BINDACE

Do not take BINDACE:

If you have ever had an unusual or allergic reaction to perindopril or any ingredient of the product.

If you are pregnant or breastfeeding.

BINDACE must not be given to children.

Take special care with BINDACE:

You should know that vomiting, diarrhoea, being on dialysis, and too little salt in your diet can cause a drop in blood pressure, which may cause lightheadedness and fainting.

If you develop swelling of the face around your lips, tongue, or throat or difficulty swallowing, you should contact your doctor immediately.

If you are elderly or have kidney disease, your doctor may need to adjust your dose.

If you are to undergo anaesthesia and / or surgery, tell your doctor that you are taking perindopril.

Do not use salt substitutes or potassium supplements while taking perindopril, unless you doctor has told you to.

To be sure this medication is helping your condition, your blood pressure will need to be checked on a regular basis. Do not miss any scheduled visits to your doctor.

Tell your doctor:

if you have kidney disease.

if you are on a special diet, such as a low-salt diet.

Taking BINDACE with food and drink:

BINDACE should be taken before a meal.

Pregnancy and Breastfeeding:

Do not use this medication if you are pregnant or planning a pregnancy or if you are breastfeeding.

BINDACE can cause birth defects in the baby if you take the medication during pregnancy. Use an effective form of birth control. Stop using this medication and tell your doctor right away if you become pregnant during treatment.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking **BINDACE**.

Taking other medicines with BINDACE:

Before taking **BINDACE**, tell your doctor if you are using any of the following medicines:

Other medicines for high blood pressure, including diuretics (medicines which increase the amount of urine produced by the kidneys)

Potassium-sparing diuretics

Potassium supplements

Ciclosporin

Non-steroidal anti-inflammatory medications such as indomethacin

If you are using any of these medicines, you may not be able to take **BINDACE**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side effects.

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines.)

HOW TO TAKE BINDACE

Always take **BINDACE** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **BINDACE** is too strong or too weak, talk to your doctor or pharmacist.

BINDACE should be taken before a meal.

The usual dosages are as follows:

High blood pressure:

The usual dosage is 4 mg taken in the morning before breakfast. After one month, this can be increased to 8 mg once a day, if required.

If you are elderly or have heart failure, your doctor will prescribe a lower dosage.

Congestive heart failure:

The usual starting dose is 2 mg once daily in the morning. Your doctor can increase this dose to 4 mg once a day.

If you take more BINDACE than you should:

The most likely effect in case of overdose is low blood pressure which can make you feel dizzy or faint.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take BINDACE:

It is important to take your medicine every day as regular treatment works better.

If you forget to take **BINDACE**, take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

5. POSSIBLE SIDE EFFECTS

BINDACE can have side effects.

Not all side effects reported for **BINDACE** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **BINDACE**, please consult your doctor, pharmacist or other healthcare professional for advice.

Get emergency medical help if you have any of these signs of an allergic reaction:

Difficulty breathing

Swelling of your face, lips, tongue, or throat

Call your doctor at once if you have any of these serious side effects:

Feeling light-headed; fainting

Yellowing of the skin or eyes

Urinating less than usual, or not at all

Palpitations

Pale skin, easy bruising or bleeding

Other side effects include: Sleep problems, mood swings, headache, dizziness, pins and needles, cough, diarrhoea, nausea, abdominal pain, dry mouth, skin rash, muscle cramps, sexual problems, disorders of the blood, lack of energy, anaemia.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF BINDACE

Store at or below 25 °C in a dry place. Do not remove the blisters from the carton until required.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF BINDACE

BINDACE 2 mg, BINDACE 4 mg, and BINDACE 8 mg:

Blister Packs:

Tablets are packed in blister packs (composed of clear PVC film and silver coloured aluminium lidding foil). Each blister contains 10 tablets. Three blisters are packed in a bag together with a silica gel sachet.

Pack size 30's: Each carton contains 3 blisters of 10 tablets each.

8. IDENTIFICATION OF BINDACE

BINDACE 2 mg

White to off-white coloured round biconvex uncoated tablets, with debossing “D” on one side and “57” on other side.

BINDACE 4 mg

White to off-white coloured capsule shaped uncoated tablets, with debossing “D” on one side and “5” & “8” on either side of the breakline on another side.

BINDACE 8 mg

White to off-white coloured round biconvex uncoated tablets, with debossing “D” on one side and “5” & “9” on either side of breakline on another side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

BINDACE 2 mg: 43/7.1.3/1039

BINDACE 4 mg: 43/7.1.3/1040

BINDACE 8 mg: 43/7.1.3/1041

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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FOR NAMIBIA ONLY:

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