

PROPOSED PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before you take PERISTAR. This leaflet tells you the main points about the medicine. If you have any questions or are worried about any of this information, please ask your doctor or pharmacist.

SCHEDULING STATUS

S3

PROPRIETARY NAME AND (DOSAGE FORM):

PERISTAR 2 (TABLETS)

PERISTAR 4 (TABLETS)

PERISTAR 8 (TABLETS)

(AND DOSAGE FORM) (TABLETS)

WHAT THIS MEDICINE CONTAINS:

Each **PERISTAR 2** tablet contains 2 mg perindopril, tert-Butylamine salt.

Each **PERISTAR 4** tablet contains 4 mg perindopril, tert-Butylamine salt.

Each **PERISTAR 8** tablet contains 8 mg perindopril, tert-Butylamine salt.

List of excipients: Hydrophobic colloidal silica, lactose monohydrate, magnesium stearate and microcrystalline cellulose.

WHAT THIS MEDICINE IS USED FOR:

PERISTAR is indicated for hypertension (high blood pressure) and for heart failure when it is not adequately controlled by other medicine.

BEFORE TAKING THIS MEDICINE:

You should not take **PERISTAR**:

- If you are a child (unless otherwise directed by your doctor).
- If you are allergic to the product or any of its components.

Do not use **PERISTAR** if you are pregnant or are planning to become pregnant. Perindopril can pass through the placenta and may influence the blood pressure of your baby. Please inform your doctor or healthcare professional if you are pregnant or planning to become pregnant.

The following medication may interact with **PERISTAR** and therefore you should notify your doctor or healthcare professional if you are taking medicines that contains any of the following before taking

PERISTAR:

- Diuretics.
- Other anti-hypertensives, or
- Other agents, including alcohol.

If you are taking medicines on a regular basis, concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

If you are pregnant or breastfeeding your baby consult your doctor, pharmacist or other health care professional before using this medicine.

HOW TO TAKE THIS MEDICINE:

Your doctor, pharmacist or healthcare professional will know best to advise you how to take your medicine.

If you have hypertension:

Perindopril should be taken before meals on an empty stomach. The recommended dosage is 4 mg taken in the morning by mouth, before breakfast. Your doctor can increase the dose to a single dose of 8 mg if necessary after one month of treatment. If you are a diabetic a dosage of 4 mg perindopril can be used. If you are an elderly patient or you have cardiac failure the dosage should be lowered. The recommended dosage is 2 mg daily.

If you have congestive heart failure:

The treatment should be started with a low dose under supervision of your doctor. The dosage will start with 2 mg orally as a single dose in the morning which may, in most instances, be increased to 4 mg.

If your kidney function is impaired:

Your doctor or healthcare professional will adjust your dosage according to your creatinine clearance.

SIDE EFFECTS AND SPECIAL PRECATIONS:

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Most people will not experience any side-effects. As with all medicines, allergic reactions may occur rarely. If you experience any of the under mentioned side-effects, tell your doctor or pharmacist.

- Headaches,
- Moo and/or sleep disturbances,
- Dizziness,
- Muscular cramps,
- Skin rash,
- Cough,
- Dry mouth,
- Nausea and diarrhoea.

If you experience swelling of the face, lips, tongue or throat **PERISTAR** should be discontinued and appropriate medical measures taken immediately. Contact your doctor or healthcare professional. Do not share medicines prescribed for you with others. In the event of over dosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

STORAGE AND DISPOSAL INFORMATION:

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

Keep the blisters in the outer cartons until required for use.

KEEP OUT OF REACH OF CHILDREN.

Return any unused medicine to the pharmacy or your healthcare professional who will dispose the medicine on your behalf.

PRESENTATION

PERISTAR 2: Transparent clear PVC/Aclar/plain aluminium foil blister strips, each containing 30 tablets. One blister strip is packed in an aluminium laminated pouch with a desiccant enclosed. The pouch is placed in an outer carton bearing the labelling requirements.

PERISTAR 4: Transparent clear PVC/Aclar/plain aluminium foil blister strips, each containing 30 tablets. One blister strip is packed in an aluminium laminated pouch with a desiccant enclosed. The pouch is placed in an outer carton bearing the labelling requirements.

PERISTAR 8: Transparent clear PVC/Aclar/plain aluminium foil blister strips, each containing 15 tablets. One blister strip is packed in an aluminium laminated pouch with a desiccant enclosed. Two pouches are placed in an outer carton bearing the labelling requirements.

IDENTIFICATION

PERISTAR 2: White to off-white, round, biconvex tablet, plain on one side and debossed '2' on other side.

PERISTAR 4: White to off-white, capsule shaped tablets, with a break line on both sides and debossed with '4' on either side of the breakline on one side of the tablets.

PERISTAR 8: White to off-white, round, biconvex tablet, plain on one side and debossed with '8' on other side.

REGISTRATION NUMBER

PERISTAR 2: 41/7.1.3/0694

PERISTAR 4: 41/7.1.3/0695

PERISTAR 8: 41/7.1.3/0696

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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Erand Gardens

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