

Predonium®

PERINDOPRIL 2 mg + INDAPAMIDE 0.625 mg

PRESENTATION AND COMPOSITION

Boxes of 10 and 30 tablets dosed at 2 mg of perindopril tert-butylamine and 0.625 mg of indapamide

PROPERTIES

FIXED DOSE COMBINATION OF AN ANGIOTENSIN CONVERTING ENZYME INHIBITOR AND A DIURETIC ACTING ON THE CORTICAL DILUTION SEGMENT (C: CARDIOVASCULAR SYSTEM).

INDICATIONS

This medicine is intended for use in the treatment of essential arterial hypertension (of unknown cause).

CONTRAINDICATIONS

This medicine **MUST NOT BE USED** in the following circumstances:

- known allergy to perindopril or to other angiotensin converting enzyme inhibitors, to indapamide and sulphonamides,
- previous history of Quincke's oedema (*a type of urticaria with sudden swelling of the face and neck*) related to taking an angiotensin converting enzyme inhibitor,
- history of Quincke's oedema due to hereditary reasons or unknown reasons,
- severe kidney impairment, serious liver disorder,
- low potassium levels (*abnormal reduction in the level of potassium in the blood*),
- dialysis,
- untreated cardiac insufficiency (*heart function impairment*),
- pregnancy or breast-feeding (see section Pregnancy and breast-feeding),
- unless your doctor advises it, this medicine must not be used in combination with lithium, potassium salts, potassium-sparing diuretics, certain medicines which may cause heart rhythm disorders, or in cases of high potassium levels (excess of potassium in the blood) or renal artery stricture,
- allergy to one of the components.

IN GENERAL, unless your doctor advises it, this medicine **SHOULD NOT**

BE USED in combination with:

- lithium,
- potassium salts

- potassium-sparing diuretics,
- allopurinol (medicine for the increased level of uric acid),
- cytostatic or immunosuppressant agents (medicines for immune reactions),
- corticosteroids,
- procainamide,
- antihypertensive agents,
- anaesthetics,
- certain medicines which can cause heart rhythm disorders,

SPECIAL PRECAUTIONS

Administration of the product should be stopped in cases of unwanted effects on the liver.

A dry cough may be produced. In such cases it is important to consult your doctor again for assessment of whether the treatment should be continued.

Tell your doctor in case of

- allergic reactions,
- hymenoptera (bees, wasps) venom desensitization treatment,
- history of swelling of the face, lips or larynx,
- hepatic disorders,
- haemodialysis.

Due to the presence of lactose, this drug should not be used if the patient has galactosemia, glucose or galactose malabsorption syndrome or a lactase deficiency (rare metabolic diseases).

PRECAUTIONS FOR USE

This medicine should be used with caution in patients with :

- disorders of electrolyte balance, diabetes, gout, hypotension or strict "salt-free" diets,
- heart or kidney failure, atherosclerosis (artery stricture), renal artery stenosis (stricture),
- in elderly subjects.

Your doctor may arrange blood tests to monitor your treatment.

If you are to undergo surgery, inform the anaesthetist that you are taking this medicine.

IF IN DOUBT, DO NOT HESITATE TO SEEK THE ADVICE OF YOUR DOCTOR OR PHARMACIST.

INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

You must tell your doctor or your pharmacist if you are receiving or have recently taken another drug, in particular lithium, potassium salts, potassium-sparing diuretics, allopurinol, cytostatic agents or immunosuppressant treatments, corticosteroids, procainamide, antihypertensive agents, anaesthetics and certain medicines which can cause heart rhythm disorders, even if it is a drug obtained without prescription.

PREGNANCY AND BREAST-FEEDING

If you discover that you are pregnant whilst taking this medicine it is absolutely vital to inform and then consult the doctor who is monitoring your pregnancy and to follow his recommendations.

You must also tell your doctor if you are intending to become pregnant. You should not breast-feed whilst taking this medicine.

AS A GENERAL RULE, YOU SHOULD ALWAYS SEEK THE ADVICE OF YOUR DOCTOR OR YOUR PHARMACIST BEFORE TAKING ANY MEDICINE IF YOU ARE PREGNANT OR BREAST-FEEDING.

DRIVERS AND MACHINE OPERATORS

Individual reactions can occur in certain patients due to a reduction in blood pressure. Consequently, the ability to drive or use machinery may be reduced.

ATHLETES

The attention of athletes is drawn to the fact that this drug contains an active ingredient that may induce a positive reaction during anti-doping control tests.

LIST OF EXCIPIENTS WITH A KNOWN EFFECT : lactose.

DOSAGE AND ADMINISTRATION

Dosage

Oral route.

The usual dose is one tablet per day.

IN ALL CASES STRICTLY COMPLY WITH YOUR DOCTOR'S PRESCRIPTION.

When and how often to take the medicine

A single dose each day, preferably in the morning before the meal.

Duration of treatment

As directed by your doctor.

IN ALL CASES STRICTLY COMPLY WITH YOUR DOCTOR'S PRESCRIPTION.

What to do in cases of overdose

The most likely event in cases of overdose is hypotension.

If marked hypotension is produced, it can be treated by lying the patient down with his/her legs raised.

If the condition continues, inform your doctor immediately.

CONSULT IMMEDIATELY YOUR DOCTOR OR YOUR PHARMACIST.

What to do if you forget to take one or more doses

Contact your doctor. Do not take two doses the next day.

SIDE EFFECTS

As with any drug this medicine may cause side effects.

- tiredness, feeling of dizziness,
- headaches, mood swings and/or sleep disturbance, cramps,
- orthostatic hypotension (drop in blood pressure upon standing up, may be accompanied by dizziness),
- allergic-type dermatological reactions, skin rashes,
- stomach pains, loss of appetite, nausea, abdominal pain, constipation, taste disturbances,
- dry cough,
- dry mouth,
- exceptionally Quincke's oedema (sudden swelling of the face and neck of allergic origin), pancreatitis,
- increased risk of dehydration in elderly patients and in patients with heart failure,
- changes in blood test results may occur, particularly loss of potassium, especially in elderly or malnourished patients; your doctor may ask you to have blood tests to monitor these parameters.

IF YOU EXPERIENCE ANY UNDESIRABLE EFFECTS NOT MENTIONED IN THIS LEAFLET, PLEASE TELL YOUR DOCTOR OR PHARMACIST.

STORAGE CONDITIONS

Do not take after the expiry date printed on the box.

Below 30°C

Keep out of reach and sight of children.



Les Laboratoires Servier – France

Manufacturer:

Les Laboratoires Servier Industrie

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