J01/98

# LUSOPRESS®

nitrendipine

**COMPOSITION**
Each tablet contains:
Active ingredients: 20 mg Nitrendipine
Excipients: Starch, Microcrystalline Cellulose, Polyvinylpyrrolidone, Sodium Lauryl Sulphate, Magnesium Stearate.

**PHARMACEUTICAL FORM AND PACK**
The printed carton contains 28 scored tablets for oral use.

**DRUG CATEGORY**
Selective calcium channel blockers, with a primarily vascular effect.

**MARKETING AUTHORISATION HOLDER**
LUSOFARMACO
Istituto Luso Farmaco d'Italia S.p.A. - Milan - Italy

**INDICATIONS**
Arterial hypertension

**CONTRAINDICATIONS**
Known hypersensitivity to the product.
Pregnancy and lactation

**SPECIAL PRECAUTIONS FOR USE**
Lusopress® must be used with caution and under the strict control of the physician in patients with renal and/or hepatic disorders and glaucoma.
Lusopress® may occasionally cause an increase in alkaline phosphatase; hepatic function should therefore be tested periodically and treatment suspended if necessary.
In the event of hypersensitivity to the product (as for example, in the event of skin rash or widespread itching), treatment with Lusopress® should be suspended.
People react in different ways to the product: some may find their ability to drive a vehicle or to work machinery is impaired. This applies particularly in the early stages of treatment in concomitance with a change in previous treatment or when tablets are taken contemporaneously with alcohol.

**DRUG AND SUBSTANCE INTERACTIONS**
When administered together with other necessary anti-hypertensive drugs, Lusopress® is generally well tolerated, although in these cases the effects of Nitrendipine may be increased.
In the case of contemporaneous administration of beta-blockers, regular medical checks are necessary, since the hypotensive effect of the product may be accentuated; this also applies in the case of concomitant treatment with Cimetidine.
The simultaneous administration of Nitrendipine and Digoxin may give rise to an increase in glycoside blood levels; possible signs or symptoms of excessive digitalis intake should therefore be carefully monitored; if necessary digoxinemia should be determined and the glycoside dosage reduced.

**SPECIAL WARNINGS**
Keep the tablets away from the light after removing them from the blister pack.

**DOSAGE AND ADMINISTRATION**
Treatment with Nitrendipine should be based on the individual patient's requirements and in accordance with the gravity of the hypertensive disorder and should always be administered under the direct control of the physician.
Unless otherwise prescribed, the recommended dosage for adults is as follows:
1 tablet a day, to be taken in the morning, or 1/2 tablet twice a day, in the morning and evening, (for a total of 20 mg of Nitrendipine a day).
In the event that a higher dosage is necessary it is possible to proceed toward a gradual increase of the daily dosage up to 1 tablet twice a day in the morning and in the evening (for a total of 40 mg of Nitrendipine a day).
In the event that a reduced dosage is necessary, 1/2 tablet (10 mg) of Nitrendipine should be taken in the morning.
Patients with chronic hepatopathy or renal failure show, respectively, delayed metabolisation and excretion of the product; it is therefore essential that dosage be adapted to the individual patient's needs, in accordance with the gravity of concomitant pathologies. In the above-mentioned cases treatment should commence with 1/4 tablet (5 mg) in the morning.

**OVERDOSE**
No toxic effects of Nitrendipine have been reported in man.
An overdose of the product usually causes excessive peripheral vasodilatation and systemic arterial hypotension. In these cases the patient should be supinated and treated accordingly. Arterial pressure should be checked frequently. The effects of calcium channel blocking can be eliminated by administering intravenous calcium gluconate.

**POSSIBLE ADVERSE EFFECTS**
The use of Nitrendipine may cause headache, flushing or a sensation of heat. The above symptoms occur mainly during the first weeks of treatment and are generally only of modest entity and tend to diminish during the course of treatment.
The onset of malleolar oedemas is caused by dilation of blood vessels which disappear when treatment is suspended.
In addition, nausea, diarrhoea, vertigo, asthenia, itching, tachycardia and palpitations have also been reported.
Treatment with Nitrendipine may cause an increase in diuresis.
Very rarely, as has been observed with other vasoactive preparations, the onset of precordialgias has been reported 15-30 minutes after product intake, some of which take the form of anginous disorders. The doctor should be advised in the event of this occurring.
The doctor or pharmacist should also be informed of any undesired effects not described in this leaflet.

Keep the tablets out of the reach of children.

The expiry date is shown on the carton.

**Attention:** Do not use the tablets after the expiry date shown on the carton.

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