

## **NIFERETARD® SR**

### **20 mg capsules**

**Dear patient,**

**Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.**

#### **Information about NIFERETARD**

Each capsule of NIFERETARD contains 20 mg nifedipine as sustained release microgranules.

Nifedipine is a calcium channel blocker. It inhibits calcium ion influx across the cell membrane of cardiac muscle and vascular smooth muscle without altering serum calcium concentrations. NIFERETARD causes arterial vasodilation which results in reduced arterial blood pressure.

NIFERETARD is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

#### **The way to take NIFERETARD**

Take NIFERETARD as directed by your physician. Do not discontinue the treatment without consulting your doctor.

Dosage and duration of treatment are individualized according to each patient's needs; the dosage must not be changed without medical advice.

NIFERETARD SR capsules should be swallowed whole and should not be chewed.

The usual recommended dosage is 1 capsule twice daily (20 mg twice daily). The dosage may be increased if necessary.

#### **Duration of treatment**

Your doctor will determine the duration of use. Do not stop the medicine without consulting your physician. If discontinuation of the drug is necessary, the dosage should be decreased gradually with close medical supervision.

#### **In case of overdose**

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

#### **In case of missed dose**

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

#### **Contraindications**

This drug is contraindicated in case of known hypersensitivity to any of the components.

#### **Precautions**

- You must inform your doctor about all previous diseases (especially heart diseases), concomitant symptoms and any other concomitant treatment.
- Inform your doctor if you experience anginal pains when you start taking this medication.
- This drug must be administered with caution in case of hepatic impairment.
- Careful monitoring of blood pressure during the initial administration and titration of the drug is suggested. Close observation is especially recommended for patients already taking medications that are known to lower blood pressure.
- It is recommended not to administer this drug during pregnancy and lactation.

#### **Associations with other medications**

Please inform your doctor if other medicines are being taken or have been taken recently.

This drug may enhance the antihypertensive effects of beta-adrenergic blocking agents although the combination is generally well tolerated.

Use with caution with digoxin, cimetidine, carbamazepine, phenobarbital, phenytoin, primidone, baclofen, cyclosporine, itraconazole, rifampicin, tricyclic antidepressants and neuroleptics.

**Adverse reactions**

This drug is usually well tolerated. Adverse effects may appear at the early initiation of treatment and usually are transient and disappear after discontinuation of the drug.

The most frequently reported adverse reactions include dizziness, flushing, headache, hypotension and peripheral edema.

Rarely reported adverse reactions include asthenia, allergic reactions, gingivitis, cramps, diarrhea, and alterations of hepatic functions.

Inform your doctor if any adverse reaction appears or becomes bothersome.

**Storage**

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

**Pack Presentation**

NIFERETARD, nifedipine 20 mg sustained release microgranules, pack of 30 capsules

**Revision date: 03/2005**

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