# DILCOR®

## Nifedipine (I.C.D.)

### COMPOSITION

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| Nifedipine (I.C.D.) | 10 mg |
| Sodium Saccharine | 0,5 mg |

Excipient: Lactose.
Other excipients: s.q. for one capsule.

### INDICATIONS

Prevention and treatment of angor pectoris.
Treatment of arterial hypertension.

### DOSAGE SCHEDULE

It is recommended that adjustment of the dosage be individualized.

**Treatment of arterial hypertension:**

The recommended initial dose is 10 mg, thrice daily (one capsule every 8 hours). If necessary, the dose may be gradually increased up to a dosage of 20 mg thrice daily (two capsules every 8 hours). In the event of hypertensive crisis 10 mg sublingual dose is recommended, which may be repeated up to a maximum of 30 mg according to the clinical response (see guidelines for correct administration) in order to achieve a quick antihypertensive effect.

**Angor pectoris:**

The recommended initial dose is 10 mg, thrice daily (one capsule every 8 hours). If necessary, the dose may be gradually increased up to 20 mg thrice daily (two capsules every 8 hours).
The recommended interval between each 20 mg dose should in all cases never be less than 2 hours.
In the event that treatment has to be discontinued, it is recommended to lower the dosage gradually under medical control.

### GUIDELINES FOR CORRECT ADMINISTRATION

Capsules should be taken orally without chewing, by following the dosage intervals established by the doctor. Medication may be taken with the meals or alone.
Sublingual administration of the drug (the capsule contents must be emptied and held under the tongue) the patients must be sitting or lying down in order to avoid dizziness which may appear owing to a sharp fall of blood pressure.

### CONTRAINDICATIONS

History of hypersensitivity to nifedipine.
Pregnancy, lactation, cardiovascular shock.

### PRECAUTIONS

The use of nifedipine in diabetic patients may require adjusment of hypoglycaemiant drug.
Precautions should be taken in case of obvious hypotension.
Precautions should be taken in patients subject to dialysis with malignant hypertension and irreversible renal impairment, as well as in patients with hypovolemia, since it may cause and obvious fall of blood pressure owing to vasodilation.

Nifedipine may limit the reaction capacity. Precautions must be taken when driving cars or other vehicles, and dangerous motor vehicles while taking nifedipine. The risk is enhanced when simultaneously taken with alcoholic beverages.
Special medical control is recommended in patients with severely depressed ventricular function or in those cases where it is necessary to associate with betablockers or digoxim, since in these cases the risk of cardiac insufficiency is higher.
This speciality contains lactose. Cases of intolerability to this drug have been described in children and adolescents. Although the quantity contained in this preparation is probably not sufficient as to release intolerability symptoms, in the event of diarrhoea the doctor has to be reported.

**INTERACTIONS**
Concurrently administration with cimetidine may increase the hypotensive effect of the medication. If necessary, nifedipine may be associated with other antihypertensive or antianginal drugs, such as beta blockers or nitrates. However, the possibility that and additive effect may lead to hypotension has to be considered. There are no clinical experience available on the effects of nifedipine and beta blocker association on left cardiac insufficiency or myocardial conduction abnormalities. Extreme precautions must be taken in such cases.
As nifedipine associated with digoxin may increase plasma levels and thus the risk of toxicity, adjustment of digoxin dosage is recommended.

**SIDE EFFECTS:**
They appear at the beginning of the treatment, however, these are generally slight. Following side effcts may arise: headache, hot flushes and face reddening, nausea, giddiness, palpitations and oedema in lower limbs. Anginal pain may exceptionally appear, as a rule 30 minutes after the administration of nifedipine; requiring in such case discontinuation of therapy.
Rarely, in long-term treatments, gum abnormalities may appear (gingival hyperplasia), and in very exceptional cases gynaecomastia; these disturbances usually disappear completely after discontinuation of treatment. Sometimes, hyperglycaemia, hepatic function failure and hepatic cholestasis may appear.

**INTOXICATION AND ITS TREATMENT**
According to the available data from experimental toxicology in animals, following symptoms may appear in case of overdosage: vomiting, cyanosis, convulsions, sweating and cardiocirculatory collapse. The treatment of such symptoms is not specific, it is limited to the steps already known, such as I.V. infusion of calciumgluconate, vasoconstrictors, monitoring of respiratory ventilation, etc.

**CONDITIONS OF STORAGE:**
The active substance is supposed to be photosensitive, thus direct sus exposure has to be avoided.

**HOW SUPPLIED**
Packages with 50 capsules.

**Under medical prescription.**

**Drugs must be kept out of the reach of children**

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