PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Nifedilong 30 mg Prolonged Release Tablets.
Nifedilong 60 mg Prolonged Release Tablets.

Each prolonged release tablet of Nifedilong 30 mg contains: Nifedipine 30 mg
Each prolonged release tablet of Nifedilong 60 mg contains: Nifedipine 60 mg
Inactive ingredients in the medicine – see section 6.
Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar. This medicine is not intended for children and adolescents under the age of 18.

1. What is the medicine intended for?

The medicine is intended for treatment of chronic and stable angina, and for treatment of hypertension.
Therapeutic class: Calcium channel blockers.

2. Before using the medicine:

☒Do not use this medicine if:

- You had a heart attack in the past month.
- You previously collapsed due to a cardiac problem (cardiogenic shock), resulting in symptoms of respiratory arrest, pallor, dry mouth and cold sweat.
- You had esophageal obstruction.
- You had surgery for removal of the colon (colectomy) and formation of a pouch from a loop of the small intestine, which is attached to the stomach wall and can be emptied by the patient (Kock Pouch), Stoma.
- Your blood pressure keeps rising despite treatment with the medicine (malignant hypertension).
- Sensitivity to one of the medicine's ingredients (specified in section 6) is known, or to a similar medicine that belongs to the dihydropyridine group.
- There is hypersensitivity to Nifedipine.
- Do not use the medicine for treatment of acute angina or an unstable angina.
- You are suffering from liver diseases.
- You are suffering from aortic stenosis.
- You are suffering from inflammations of the digestive system (inflammatory bowel disease or Crohn's disease).
- Do not use together with the antibiotic Rifampicin.
- You should not drink grapefruit juice during the treatment period.
- You are suffering from bowel obstruction or narrowing.

❗Special warnings regarding the use of the medicine:

- You should be careful if you are suffering from low blood pressure and are taking Nifedilong for treatment of angina - the medicine may cause further drop in blood pressure.
- Care should be taken with patients with heart diseases, when the heart is unable to cope with increased effort.
- In diabetic patients, use of Nifedilong may cause changes and dosage adjustment in sugar-lowering agents.
- Care should be taken with renal dialysis patients. If you are suffering from very high blood pressure with small blood volume, treatment with Nifedilong may cause a sharp drop in blood pressure.
- You should tell the doctor if the angina worsens during treatment with the medicine (stronger pain or higher frequency) within hours or days, or if you suffered from angina, or if more intense shortness of breath or swelling in the ankles appeared after administration of the first tablet.
- You should tell the doctor if: you are going to have a urine test, you are going to have an x-ray with Barium (a contrasting agent), or if you are a man and are unsuccessful in fathering a child by in-vitro fertilization (Nifedilong may impair sperm function).
- If you are sensitive to any type of food or medicine, inform your doctor before starting treatment with this medicine.
- The tablets contain lactose.

❗If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist. Especially inform the doctor or pharmacist if you are taking:

- Rifampicin - an antibiotic for treatment of tuberculosis (see also "do not use this medicine if").
- Medicines for epilepsy - Carbamazepine, Phenytoin, Valproic acid and Phenobarbital.
- Medicines for AIDS (such as: Indinavir, Nelfinavir, Ritonavir, Saquinavir or Amprenavir).
- Medicines for treatment of fungal infection (such as: Ketoconazole, Itraconazole or Fluconazole).
- Other medicines for lowering blood pressure (e.g. beta blockers).
- Magnesium sulfate injections during pregnancy (may cause a sharp drop in blood pressure).
- Medicines for cardiac diseases - Digoxin, Diltiazem, Quinidine.
- Cimetidine (for treatment of heartburn), Cisapride (for treatment of reduced motility of the digestive system).
- Fluoxetine, Nefazodone (for treatment of depression).
- Erythromycin (an antibiotic of the macrolide family).
- Quinupristin/Dalfopristin (a combination of antibiotic medicines).
- Tacrolimus (for prevention of transplant rejection).

❗Using Nifedilong and food

- It is recommended to not drink alcoholic beverages during treatment with the medicine. Using this medicine together with alcohol may impair alertness.
- You should avoid drinking grapefruit juice or eating grapefruits during treatment with this medicine. Grapefruits may cause an elevation of Nifedipine in the blood, the effect passes after 3 days.
- The medicine may be taken with or without food.

❗Pregnancy and breastfeeding
If you are pregnant, think that you are pregnant, or planning to become pregnant, you should consult a doctor before starting to use the medicine.
Do not use the medicine if you are breastfeeding. If you need to use the medicine, you should stop breastfeeding before starting to use it.

❗Driving and operating machinery
The medicine may cause dizziness, weakness, fatigue or visual disturbances. You should be careful when driving and/or when operating a machine that requires alertness. These effects usually occur in the beginning of treatment with the medicine, after changing the type of tablets or when drinking alcohol.

3. How should you use the medicine?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.
Do not chew! The tablet should be swallowed whole with some water. The medicine may be taken with or without food.
The medicine should be taken every day at the same time, preferably in the morning.
The tablet should not be halved or crushed.
This is a slow-release tablet, halving or crushing it may cause an overdose due to immediate release of the medicine.

- **If you accidentally took a higher dosage** the following will appear: signs of impaired consciousness up to loss of consciousness, severe hypotension, slowing or acceleration of heart rate, high blood sugar level, low blood oxygen levels, elevation of blood acidity (acidosis) and pulmonary edema.
- If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.
- **If you forgot to take the medicine** on time, take the next dose immediately and continue taking the medicine regularly. You should wait at least 12 hours between doses. Do not take a double dose in order to compensate for a forgotten dose.
- You should continue taking the medicine as recommended by the doctor.
- Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist.
- **If you stop taking the medicine** the symptoms of angina and hypertension may return.
- If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.
- This medicine is not intended for children and adolescents under the age of 18, since information about the efficacy and safety of the medicine in this population is limited.

4. Side effects:

As with any medicine, using Nifedilong may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Contact the doctor immediately and do not take the next dose if you experience the following side effects:

- A sudden and severe allergic reaction which may be life-threatening and manifested in difficulty breathing, drop in blood pressure, fast heartbeat, swelling that may cause airways obstruction.
- Rapid heartbeat, shortness of breath and difficulty breathing, mild to moderate allergic reaction, itching and rash.

You should contact a doctor immediately before continuing the treatment if you are sensing one of the following effects which may be a sign of a severe reaction:

- A skin reaction or appearance of blisters, skin exfoliation and/or a reaction of mucous membranes (in the mouth, nose, penis or vagina) (Toxic epidermal necrolysis).

Common side effects (side effects that occur in 1 out of 10 patients):
Headache, flushing, bad general feeling, constipation, swelling - especially of the ankles and legs.
Uncommon side effects (side effects that occur in 1 out of 100 patients):
Abdominal pain, unspecified pain, chills, orthostatic hypotension (symptoms include fainting, dizziness, strong palpitations, blurry vision and sometimes confusion), fainting, irregular palpitations, dry mouth, indigestion, flatulence, nausea, muscle cramps, swollen joints, sleep disturbances, anxiety and restlessness, reddening of the skin, nosebleed, stuffy nose, vertigo, migraine, dizziness, tremor, increased frequency of urination, pain or difficulty in urination, difficulty to achieve or maintain erection, blurry vision, temporary elevation in liver enzymes.
Rare side effects (side effects that occur in 1 out of 1000 patients):
Sensation of tingling, inflammation of the gums, sensitivity or swelling of the gums, bleeding gums.
Side effects occurring at an unknown frequency:
Abdominal pain or distress caused by a foreign mass (may require surgery), swallowing difficulties, abdominal pain caused by bowel obstruction or peptic ulcers, vomiting, eye pain, chest pain, a decrease in the number of white blood cells (leukopenia), a more severe decrease of white blood cells called granulocytes (agranulocytosis), elevated blood sugar levels, a decrease in the skin's sensation of pain or touch, sleepiness, heartburn, indigestion, yellowing of the skin or the white part of the eye (jaundice), an allergic reaction to sunlight, purple-red patches on the skin (purpura), muscle and joint pains.
If one of the side effects worsens, or when you suffer from a side effect not mentioned in the leaflet, consult a doctor.
Reporting side effects:
Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- Store in the original package in order to protect from light and moisture.

6. Additional information

In addition to the active ingredient the medicine also contains:
Talc, Povidone, Lactose monohydrate, Hypromellose, Carbomer, Silica Colloidal Anhydrous, Magensium Stearate, Eudragit E, Titanium Dioxide, Macrogol 4000, Ferric oxide red.
Each prolonged release tablet of Nifedilong 30 mg contains 15 mg of lactose monohydrate.
Each prolonged release tablet of Nifedilong 60 mg contains 30 mg of lactose monohydrate.
A prolonged-release tablet of Nifedilong 30 mg is a round, pale-red, biconvex tablet. Each pack contains blisters of 10 tablets. Amount of tablets in the package: 10, 20, 30, 60 or 100.
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Not all package sizes may be marketed.
License holder/importer: CTS Chemical Industries Ltd., P.O. box 385, Kiryat Malachi.
Manufacturer: Valpharma S.A, San Marino,Italy.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1378931415, 1372131416.
This leaflet was checked and approved by the Ministry of Health in: 01/2017.