**PATIENT INFORMATION LEAFLET**
**(NEPIN-SR-20) NIFEDIPINE SUSTAINED RELEASE TABLETS 20 MG**
**[Nifedipine]**

**Read all of this leaflet carefully before you start using this medicine.**
Keep this leaflet. You may need to read it again.
If you have any further questions, ask your physician, health care provider or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist.

**WHAT IS IN THIS LEAFLET**:



## 1. WHAT NIFEDIPINE SUSTAINED RELEASE TABLETS IS AND WHAT IT IS USED FOR

It contain active ingredient nifedipine is a calcium ion influx inhibitor (slow channel blocker or calcium ion antagonist) which inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle without altering serum calcium concentrations. Nifedipine brings about an improvement in the oxygen supply to the heart muscle with simultaneous reduction of oxygen requirements, thereby exerting an antianginal effect. It is used to treatment in hypertension, and in prophylaxis of angina pectoris.

## 2. BEFORE YOU USE NIFEDIPINE SUSTAINED RELEASE TABLETS

Do not use it if you are allergic to nifedipine or any of the other ingredients of this medicine. It is contraindicated in pregnancy and lactation, patients with hepatic impairment, patients with history of gastro-intestinal obstruction oesophageal obstruction or any degree of decreased lumen diameter of the gastro-intestinal tract, patients with inflammatory bowel disease, in cases of cardiogenic shock, clinically significant aortic stenosis, unstable angina, and myocardial infraction. Do not take if any of the above apply to you. If you are not sure, talk to your physician, pharmacist or nurse before having nifedipine sustained release tablets.

**Take special care with nifedipine sustained release tablets**: Talk to your physician before taking nifedipine sustained release tablets. Fixed left ventricular outflow obstruction, poor cardiac reserve, large doses of b-blockers, diabetes, CCF, hepatic impairment, severe aortic stenosis. Avoid abrupt withdrawal of drug.

**Warnings and Precautions:** Caution should be exercised in patients with hypotension as there is a risk of further reduction in blood pressure. It may be used in combination with beta-blocking drugs and other antihypertensive agents but the possibility of an additive effect resulting in postural hypotension should be borne in mind. It should be used with caution in patients whose cardiac reserve is poor. Deterioration of heart failure has occasionally been observed with nifedipine. Diabetic patients taking Nifedipine may require adjustment of their control. In dialysis patients with malignant hypertension and hypovolaemia, a marked decrease in blood pressure can occur.

**Paediatric:** Nifedipine is not recommended for use in children.

**Using other medicines:** Concurrent use with Increases digoxin blood levels. Concurrent use with beta-blockers leads to hypotension, angina and cardiac failure Synergism with Beta-blockers. Reverse depression of cardiac function caused by Beta-blockers. Cimetidine increase bioavailability and potentiates hypotensive action. Upon co-administration with macrolide-antibiotics (e.g., erythromycin), anti-HIV protease inhibitors (e.g., ritonavir), azole antimycotics (e.g., ketoconazole), the antidepressants, nefazodone and fluoxetine, quinupristin/dalfopristin, valproic acid, the blood pressure should be monitored and, if necessary, a reduction of the nifedipine dose should be considered. Avoid abrupt withdrawal of drug. Do not start taking nifedipine sustained release tablets within 3 days of drinking grapefruit juice or eating grapefruit. Tell your doctor if you have had grapefruit or grapefruit juice in this time. Also, do not drink grapefruit juice or eat grapefruit whilst taking nifedipine sustained release tablets. Grapefruit juice is known to increase the blood levels of the active ingredient, nifedipine. This effect can last for at least 3 days.

**Using nifedipine sustained release tablets with food and drink:** Patients can take this medicine with or without food. Swallow tablet whole, do not bite, chew or divide.

**Pregnancy and breast-feeding:** Before taking any medicine for advice consult to direction of physician. **Pregnancy:** It is contraindicate in pregnancy and lactation therefore it should not be used during pregnancy. **Use in breast-feeding:** No data are available, it is contraindicate in pregnancy and lactation therefore, it should not be used during breastfeeding infants.

**Driving and using machines:** There are possible side effects associated with nifedipine sustained release tablets, such as it may cause make you feel dizzy, faint, extremely tired or have visual disturbances. Do not drive or operate machinery if you are affected in this way. This may be more likely when you first start treatment, if you change tablets, or if you have drunk alcohol.

**Important information about some of the ingredients of nifedipine sustained release tablets contains**: Each film coated tablet contains lactose monohydrate, patients with rare hereditary problems of galactose intolerance, total-lactase deficiency or glucose-galactose malabsorption should not take this medicine. Talk to your physician.

## 3. HOW TO USE NIFEDIPINE SUSTAINED RELEASE TABLETS

Always take your dose of nifedipine sustained release tablets exactly as direction by physician or a nurse or health care provider or pharmacist has told you, if you are not sure. Do not change your usual dose without talking to your physician.

**How nifedipine sustained release tablets will be given to you: Method of administration:** For Oral Use Only. Patients can take this medicine with or without food. Swallow tablet whole, do not bite, chew or divide. **The usual recommended doses: In the management of the hypertension**, nifedipine sustained release tablets are given in the doses of 10-40 mg twice a daily, 30-90 mg once a daily, or 20-100 mg daily, depending on the preparation used. **In the management of angina pectoris,** nifedipine sustained release tablets are given in the doses of 10-40 mg twice a daily or 30 to 90 mg once daily, depending on the preparation. **For Elderly Patients:** Dose of nifedipine may need to be reduced in the elderly and with impaired liver function. Titrate over a 7 to 14 days period starting with 30 mg once daily. Base upward titration on therapeutic efficacy & safety. Usual maintenance dose is 30 to 60 mg once daily. Titration dose more than 90 mg daily is not recommended. Closely monitor blood pressure since severe hypotension can occur. The pharmacokinetics of nifedipine are altered in the elderly so that lower maintenance doses of nifedipine may be required compared to younger patients.

**Use in children:** It is not recommended for use in children.

**If you more nifedipine sustained release tablets than you should:** the over dosage is unlikely to oral route. By accident, anyone take this medicine, experience with nifedipine overdosage is limited, generally, overdosage with nifedipine leading to pronounced hypotension. Contact your physician straight away.

**If you forget to nifedipine sustained release tablets:** It is important to take nifedipine sustained release tablets as prescribed by your physician. Take your normal dose immediately and continue taking your tablets at the usual time of day, waiting at least 12 hours before taking the next dose. Do not take a double dose to make up for the missed dose. If you have any further questions on the use of this product, ask your physician, health care provider or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your physician, health care provider or pharmacist. Like all medicines, it can cause side effects, although not everybody gets them. Following adverse effects have been reported with oral administration of nifedipine: CNS: Dizziness, light-headedness, headache, asthenia, fatigue, nervousness, sleep disturbances, blurred vision. GI: Nausea, diarrhea, constipation, cramps, flatulence, hepatic injury. CV: Peripheral edema, angina, hypotension, arrhythmias, AV block, asystole. Dermatological: Flushing, rash, dermatitis, pruritis, urticaria. Other: Nasal congestion, cough, fever, chills, shortness of breath, muscle cramps, joint stiffness, sexual difficulties.

## 5. HOW TO STORE NIFEDIPINE SUSTAINED RELEASE TABLETS

Keep this medicine out of the sight and reach of children. Do not store above 30°C. Protect from light. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

## 6. FURTHER INFORMATION

It contain active substances as Nifedipine BP. Excipients as: Lactose Monohydrate BP, Hypromellose (Metolose 90-SH-4000) BP, Maize Starch BP, Povidone (PVPK-90) BP, Isopropyl Alcohol BP, Purified Talc BP, Colloidal Anhydrous Silica BP, Magnesium Stearate BP, Sodium Starch Glycolate (Type-A) BP, Hypromellose (Methocel 15) BP, Titanium Dioxide BP, Colour Carmosine Supra HIS, Colour Susnet Yellow Lake HIS, Colour Indigo Carmine Lake HIS, Diethyl Phthalate BP, Dichloromethane BP. Pack size: Purple coloured, round shaped, biconvex, film coated sustained release tablets, plain on both sides. Nifedipine Sustained Release Tablets filled in Blister packed. Such 10 tablets are packed in blister pack. Such 10 blisters are packed in a printed carton with packing insert.

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