

NICARDIN-SR TABLETS

Nifedipine SR Tablets

COMPOSITION:

Each Sustained Release tablet contains: Nifedipine BP 20mg.

PROPERTIES AND ACTIONS:

Nicardin-SR[®] Tablets contain Nifedipine which is a dihydropyridine calcium-channel blocking agent. Calcium-channel blockers, also known as calcium antagonist, calcium-entry blockers, and slow-channel blockers, inhibit the cellular influx of calcium which is responsible for maintenance of the plateau phase of the action potential. Thus nifedipine primarily affects tissues in which depolarisation is dependent upon calcium rather than sodium influx, and these include vascular smooth muscle, myocardial cells and cells within the sino-atrial (SA) and atrioventricular (AV) nodes. The main actions of nifedipine include dilatation of coronary and peripheral arteries and arterioles, a negative inotropic action, reduction of heart rate, and slowing of AV conduction. Nifedipine, unlike verapamil or diltiazem, has little or no action at the SA or AV nodes, and negative inotropic activity is rarely seen at therapeutic doses.

Administration of nifedipine results primarily in vasodilation, with reduced peripheral resistance, blood pressure, and afterload, increased coronary blood flow, and a reflex increase in heart rate. This in turn results in an increase in myocardial oxygen supply and cardiac output. Nifedipine has no antiarrhythmic activity.

INDICATIONS:

Nicardin-SR[®] Tablets are used alone or in combination with other agents such as thiazide diuretics and beta-blockers in the management of hypertension. They are also used in the treatment and prophylaxis of angina pectoris, particularly when a vasospastic element is present, as in Prinzmetal's angina. Nifedipine has also been used in the treatment of Raynaud's syndrome.

DOSEAGE AND ADMINISTRATION:

Nicardin-SR[®] Tablets are administered by the oral route either with or after meals as follows:

Indications	Dosage
Hypertension	10mg twice daily, increased if necessary to up to 40mg twice daily.
Prophylaxis of angina pectoris, or alternative in the treatment of hypertension	10mg three times daily, increased if necessary to 20mg three times daily, or more. A maximum daily dose of 180mg has been recommended but doses greater than 120mg daily are reported to be necessary only rarely.

Nicardin-SR[®] Tablets is taken at the usual dose rate of one tablet twice daily for hypertension and angina prophylaxis. The usual maintenance dosage may be increased up to 40mg twice daily. In elderly patients, those on concomitant medication, or those with hepatic dysfunction; the recommended initial dose is half the above doses.

PRECAUTIONS AND WARNINGS:

1. Nicardin-SR[®] Tablets should be used with caution in patients with hypotension and in patients whose cardiac reserve is poor.
2. The dose of Nicardin-SR[®] Tablets should be reduced in elderly patients and in patients with hepatic impairment, while diabetic patients may need to adjust their antidiabetic treatment when receiving nifedipine.
3. Nicardin-SR[®] Tablets should not be used in cardiogenic shock and it should be avoided in patients with severe aortic stenosis since its use may increase the risk of developing heart failure.
4. Nicardin-SR[®] Tablets should be discontinued in patients who experience ischaemic pain following its administration.

ADVERSE EFFECTS:

The most common adverse effects of nifedipine are associated with the vasodilatory action, such as dizziness, flushing, headache, hypotension, and peripheral oedema. Gastro-intestinal disturbances, increased frequency of micturition, lethargy, eye pain, and mental depression have also occurred. A paradoxical increase in ischaemic chest pain may occur at the start of treatment and in a few patients excessive fall in blood pressure has led to cerebral or myocardial ischaemia or transient blindness.

There have been reports of rashes, fever and abnormalities in liver function due to hypersensitivity reactions. Gingival hyperplasia has been reported but is often reversible on drug withdrawal.

LEGAL CATEGORY: Prescription Only Medicine (POM).

STORAGE CONDITIONS: Store in a dry place below 30°C. Protect from light. Keep out of reach of children.

SHELF LIFE: As per the product label.

PRESENTATION: Nicardin-SR[®] Tablets are available in blister packs of 60's, 10 x 10's and in bulk packs of 1000's.

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