

FLOCARD

(Nicorandil Tablets BP)

10mg
20mg
Tablets

فلوکارڈ
ٹا بلیٹس
گولیاں
(نائیکورینڈیل بی پی)

COMPOSITION:

Each tablet contains:
Nicorandil BP ... 10mg or 20mg.
[BP Specs.]

DESCRIPTION:

FLOCARD tablets are formulated for oral administration. Nicorandil belongs to a group of drugs known as potassium channel activators. It is used to relieve and prevent angina by reducing the workload of the heart and increasing its blood supply. Nicorandil also opens up blood vessels elsewhere in the body to reduce the amount of work, the heart has to do, to pump blood through out the body.

CLINICAL PHARMACOLOGY:

Pharmacokinetics: Nicorandil is well absorbed from GI tract with no significant first-pass metabolism. Maximum plasma concentrations are achieved within 30 to 60 minutes and are directly related to the dosage. Metabolism is done mainly by denitration of the molecule into the nicotinamide pathway with less than 20% of an administered dose being excreted in the urine. The main phase of elimination has a half-life of about 1 hour. Nicorandil is only slightly bound to plasma proteins. No clinically relevant modifications in the pharmacokinetic profile have been seen in the elderly or in patients with liver disease or chronic renal failure.

Pharmacodynamics:

Nicorandil provides a dual mode of action leading to relaxation of vascular smooth muscle. A potassium channel opening action provides arterial vasodilation, thus reducing after load, while the nitrate component promotes venous relaxation and a reduction in preload. Nicorandil has a direct effect on coronary arteries. The overall action improves blood flow to post-stenotic regions and the oxygen balance in the myocardium.

INDICATIONS:

FLOCARD tablets (Nicorandil) are indicated for the following:
1. The prevention and long term treatment of chronic stable angina pectoris.
2. A reduction in the risk of acute coronary syndromes in patients with chronic stable angina.

Angina is regarded as stable if it has been occurring over several weeks without major deterioration and occurs in a predictable pattern. Angina in such patients occurs when the heart needs more blood for example, with a particular level of physical activity or when patient becomes emotionally stressed.

CONTRA-INDICATIONS:

Nicorandil tablets are contra-indicated in patients with cardiogenic shock, left ventricular failure with low filling pressures and in hypotension. It is also contra-indicated in patients who have demonstrated an idiosyncratic response or hypersensitivity to Nicorandil or any of the excipients. Due to the risk of severe hypotension, the concomitant use of **Nicorandil** tablet and phosphodiesterase 5 inhibitors (e.g. sildenafil, tadalafil, vardenafil) is contra-indicated.

DOSAGE AND ADMINISTRATION:

Adults: The recommended starting dose is 10mg **Nicorandil** tablets twice daily, although 5mg twice daily may be employed in patients particularly susceptible to headache. Subsequently the dosage should be titrated upward depending on the clinical response. The usual therapeutic dosage is in the range of 10 to 20mg **Nicorandil** tablets twice daily, although up to 30mg twice daily may be employed if necessary.

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Elderly: There is no special requirement for dosage reduction in elderly patients. As with all medicines, the lowest effective dosage should be used.

Children: A pediatric dosage has not been established and use of **Nicorandil** tablet is not recommended.

OVERDOSE:

Acute overdosage is likely to be associated with peripheral vasodilation, decreased blood pressure and reflex tachycardia. Cardiac function should be monitored and general supportive measures employed. If necessary, circulating plasma volume should be increased by infusion of suitable fluid. In life-threatening situations, administration of vasopressors should be considered. There is no experience of massive overdosage in humans.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

The use of **Nicorandil** tablet should be avoided in patients with depleted blood volume, low systolic blood pressure, acute pulmonary oedema or acute myocardial infarction with acute left ventricular failure and low filling pressures.

Therapeutic doses of **Nicorandil** tablet may lower the blood pressure of hypertensive patients and therefore **Nicorandil** tablet, as with other antianginal agents, should be used with care when prescribed with antihypertensive drugs. Alternative therapy should be considered if persistent aphthosis or severe mouth ulceration occurs.

DRUG INTERACTIONS:

No pharmacological or pharmacokinetic interactions have been observed in humans or animals with β -blockers, digoxin, rifampicin, cimetidine, nicoumalone, a calcium antagonist or a combination of digoxin and frusemide. Nevertheless, there is the possibility that **Nicorandil** may potentiate the hypotensive effects of other vasodilators, tricyclic antidepressants or alcohol.

PREGNANCY:

It should not be used in pregnant patients unless there is no safer alternative.

LACTATION:

As it is not known whether **Nicorandil** is excreted in human milk, breastfeeding should be avoided by lactating patients who require therapy.

UNDESIRABLE EFFECTS:

The most frequent effect to be anticipated is headache, usually of a transitory nature, especially when treatment is initiated. Cutaneous vasodilation with flushing is less frequent. Nausea, vomiting, dizziness and a feeling of weakness have been reported occasionally. Myalgia and different types of rash have been reported rarely. There have been very rare reports of angioedema and hepatic function abnormalities.

Hypotension may occur at high therapeutic doses. An increase in heart rate may occur at high doses.

Rare cases of persistent aphthosis or mouth ulcers which were occasionally severe have been reported.

INSTRUCTIONS:

Store below 25°C in a dry place. Protect from heat, light & moisture. Keep out of the reach of children.

PRESENTATION:

FLOCARD 10mg tablets are available in Alu Alu pack of 10's x 1.
FLOCARD 20mg tablets are available in Alu Alu pack of 10's x 1.

ہدایات: خشک جگہ پر ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔



Manufactured by:
NABIQASIM INDUSTRIES (PVT.) LTD.
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