ASPIN
An OBS Group Company

IKODIL® Tablets ایکوڈل
(Nicorandil)

DESCRIPTION:

Nicorandil belongs to a group of drugs known as potassium channel activators. It is used to relieve and prevent angina by reducing 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 around the body.

IKODIL® TABLET 10 mg
Each tablet contains:
Nicorandil, B.P.....10 mg
IKODIL® TABLET 20 mg
Each tablet contains:
Nicorandil, B.P.....20 mg

PHARMACOLOGICAL PROPERTIES:

Pharmacodynamic properties:
Nicorandil provides a dual mode of action leading to relaxation of vascular smooth muscle. A potassium channel opening action provides arterial vasodilation, thus reducing afterload, 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.

Pharmacokinetic properties:
Nicorandil is well absorbed with no significant first-pass metabolism. Maximum plasma concentrations are achieved in 30 to 60 minutes and are directly related to the dosage. Metabolism is 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.

INDICATIONS:

IKODIL® tablets 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 and at least one of the following risk factors:
• Previous MI
• Previous CABG
• CHD on angiography or a positive exercise test together with one of the following: LVH on ECG, left ventricular dysfunction, Age 65, diabetes mellitus (type I or II excluding those on sulphonylureas), hypertension or documented vascular disease.

CONTRAINDICATIONS:

IKODIL® is contraindicated in patients with cardiogenic shock, left ventricular failure with low filling pressures and in hypotension. It is also contraindicated in patients who have demonstrated an idiosyncratic response or hypersensitivity to nicorandil . Due to the risk of severe hypotension, the concomitant use of IKODIL® and phosphodiesterase 5 inhibitors (e.g. sildenafil, tadalafil, vardenafil) is contraindicated.

INTERACTIONS:

• No pharmacological or pharmacokinetic interactions have been observed when nicorandil was concomitantly administered with beta-blockers, digoxin, rifampicin, cimetidine, acenocoumarol, a calcium antagonist or a combination of digoxin and furosemide. Nevertheless, there is the possibility that nicorandil may potentiate the hypotensive effects of other vasodilators, tricyclic antidepressants or alcohol.

• Therapeutic doses of IKODIL® (nicorandil) may lower the blood pressure of hypertensive patients and IKODIL® therefore, as with other antianginal agents, should be used with care when prescribed with antihypertensive drugs.

• **Corticosteroids:** GI perforations with the concomitant use of nicorandil and corticosteroids have been reported. Caution is advised when concomitant use is considered.

PRECAUTIONS:

• The use of IKODIL® 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.

• Alternative therapy should be considered if persistent aphtosis or severe mouth ulceration occurs.

• Caution is advised for the use of IKODIL® in patients with glaucoma.

• It should be used with caution in patients with serious diabetes, renal or hepatic dysfunction.

PREGNANCY AND LACTATION:

Pregnancy: Animal studies have not revealed any harmful effect of nicorandil on the foetus although there is no experience in humans. 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.

ADVERSE REACTIONS:

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 persistant aphthous or mouth ulcers which were occasionally severe have been reported.

DOSAGE AND ADMINISTRATION:

Route of administration: oral

Adults: The recommended starting dose is 10 mg IKODIL® twice daily, although 5 mg 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 10 to 20 mg IKODIL® twice daily, although up to 30 mg twice daily may be employed if necessary.

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 paediatric dosage has not been established and use of IKODIL® is not recommended.

OVERDOSAGE:

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.

INSTRUCTIONS:

- To be sold on the prescription of a registered medical practitioner only.
- Store below 25°C. Avoid exposure to light and moisture.
- Use medicine within 30 days after opening of blister.
- Keep out of the reach of children.

ہدایات:

صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔ ۲۵ ڈگری سینٹی گریڈ سے کم درجۂ حرارت پر رکھیں۔ دوا کو روشنی اور نمی سے بچائیں۔ بلسٹر کے کھلنے کے بعد دوا کو ۳۰ دن کے اندر استعمال کریں۔ بچوں کی پہنچ سے دور رکھیں۔

PRESENTATION:

IKODIL® 10 mg tablets in a blister pack of 1 x 10's.
IKODIL® 20 mg tablets in a blister pack of 1 x 10's.

MANUFACTURED BY:

ASPIN
An OBS Group Company

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PIL-IK-0117/1
PAK-IKD-T-0814