NIKORAN OD

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only Abbreviated Prescribing information for NIKORAN OD [Nicorandil I.P. 10 /20mg sustained release tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Nicorandil belongs to other vasodilators used in cardiac disease pharmacotherapeutic group. Potassium channel opening action provides arterial vasodilation, thus reducing afterload, while the nitrate component promotes venous relaxation and a reduction in preload.

INDICATION: For the treatment of chronic stable angina pectoris.

DOSAGE AND ADMINISTRATION: Orally administered. **Adults**: The recommended starting dose is 10mg nicorandil twice daily. 5mg twice daily may be employed in patients susceptible to headache. The usual therapeutic dosage is in the range 10 to 20mg nicorandil twice daily, although up to 30mg twice daily may be employed if necessary. **Elderly**: lowest effective dose is recommended. **Children**: Not recommended

CONTRAINDICATION: In patients with hypersensitivity to nicorandil or any of the excipients, must not be used in the case of cardiogenic shock, hypotension or left ventricular failure with low filling pressure and concurrent use of phosphodiesterase 5 inhibitors (e.g. sildenafil, tadalafil, vardenafil) is contraindicated since it can lead to a serious drop in blood pressure.

WARNINGS & PRECAUTIONS: Gastrointestinal ulcerations, skin and mucosal ulceration, gastrointestinal perforations with concomitant use of steroids, caution should be exercised in patients with blood volume depletion, low systolic blood pressure (e.g below 100 mm Hg), acutepulmonary oedema or acute myocardial infarction with acute left ventricular failure and low filling pressures and with other blood pressure lowering agents and patients should be to keep the tablets in their blister until intake because of hygroscopic nature.

DRUG INTERACTIONS: Corticosteroids, phosphodiesterase 5 inhibitors, with antihypertensive agents or other medicinal products with blood-pressure-lowering effect (e.g vasodilators, tricyclic antidepressants, alcohol)

ADVERSE REACTIONS: Headache particularly during the first few days of treatment, dizziness, increase in heart rate following the administration of high doses, cutaneous vasodilation with flushing, nausea and vomiting, feeling of weakness, rash, pruritis, angio-oedema, rectal bleeding, mouth ulcers, hepatitis, cholestasis, or jaundice and myalgia.

MARKETED BY:



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IN/NIKORAN OD 10,20 mg/NOV-2015/02/ABPI

(Additional information is available on request)