

## VASOTRATE 10,20

### For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for **VASOTRATE 10,20** [Isosorbidedemonitrate I.P. 10 mg/20 mg tablets] [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

**PHARMACOLOGICAL PROPERTIES:** The principal pharmacological action of isosorbide mononitrate is relaxation of vascular smooth muscle and consequent dilatation of peripheral arteries and veins, especially the latter. Dilation of the veins promotes peripheral pooling of blood and decreases venous return to the heart, thereby reducing left ventricular end-diastolic pressure and pulmonary capillary wedge pressure (preload). Arteriolar relaxation reduces systemic vascular resistance, systolic arterial pressure, and mean arterial pressure (afterload). Dilatation of the coronary arteries also occurs.

**INDICATION:** Treatment of coronary heart disease and the prophylaxis of angina pectoris, follow up treatment of myocardial infraction pulmonary hypertension.

**DOSAGE AND ADMINISTRATION:** The recommended regimen of isosorbide mononitrate tablets, USP is 20 mg twice daily, with the doses seven hours apart. A starting dose of 5 mg (½ tablet of the 10 mg dosing strength) might be appropriate for persons of particularly small stature but should be increased to at least 10 mg by the second or third day of therapy. Dosage adjustments are not necessary for elderly patients or patients with altered hepatic or renal function.

**CONTRAINDICATION:** Do not use in patients with known allergy to any components. Patients who are taking certain drugs for erectile dysfunction (phosphodiesterase inhibitors), such as sildenafil, tadalafil, or vardenafil, soluble guanylate cyclase stimulator riociguat.

**WARNINGS & PRECAUTIONS:** Amplification of the vasodilatory effects of isosorbide mononitrate by sildenafil can result in severe hypotension. It should therefore be used with caution in patients who may be volume depleted or who, for whatever reason, are already hypotensive. Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy. Treatment with isosorbide mononitrate may be associated with light-headedness on standing, especially just after rising from a recumbent or seated position. This effect may be more frequent in patients who have also consumed alcohol.

**DRUG INTERACTIONS:** phosphodiesterase inhibitors, riociguat and calcium channel blockers.

**ADVERSE REACTIONS:** Headache, fatigue, upper respiratory infection, pain, dizziness, nausea, cough, rash, abdominal pain, allergic reaction, cardiovascular disorder, chest pain, diarrhea, flushing, emotional lability, pruritus, acute myocardial infarction, apoplexy, arrhythmias, bradycardia, edema, hypertension, hypotension, pallor, palpitations, tachycardia, sweating, anorexia, dry mouth, dyspepsia, thirst, vomiting, decreased weight, amblyopia, back pain, bitter taste, muscle cramps, neck pain, paresthesia, susurrus aurium, anxiety, impaired concentration, depression, insomnia, nervousness, nightmares, restlessness, tremor, vertigo, asthma, dyspnea and sinusitis.

### MARKETED BY:



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(Additional information is available on request)