

Information For the User
Diluted Isosorbide Dinitrate 20 mg + Hydralazine 37.5 mg Tablet

Isofyle H tablet

Brand Name: Isofyle H Tablet

Composition:

Each uncoated tablet contains:

Diluted Isosorbide Dinitrate IP equivalent to Isosorbide Dinitrate 20 mg

Hydralazine Hydrochloride IP equivalent to Hydralazine 37.5 mg

Therapeutic Indication:

Indicated for the treatment of heart failure, especially in patients who cannot tolerate ACE inhibitors or ARBs

Helps reduce symptoms and improve exercise tolerance in chronic congestive heart failure

Useful in patients with heart failure with reduced ejection fraction (HFrEF), particularly in certain ethnic populations

Mechanism of Action:

Isosorbide Dinitrate is a nitrate vasodilator that relaxes vascular smooth muscle, reducing preload by venous dilation and decreasing myocardial oxygen demand

Hydralazine is a direct-acting arterial vasodilator that reduces afterload, decreasing systemic vascular resistance and improving cardiac output

The combination provides dual vasodilation — both venous and arterial — which is beneficial in heart failure

Dosage & Administration:

Usual adult dose: one tablet two to three times daily or as directed by the physician

Dosage may be titrated based on clinical response and tolerability

Swallow the tablet whole with water

Contraindications:

Hypersensitivity to nitrates, hydralazine, or related compounds

Coronary artery disease or mitral valve rheumatic heart disease

Severe hypotension

Concomitant use with phosphodiesterase inhibitors

Warnings & Precautions:

May cause postural hypotension, especially in elderly or volume-depleted patients

Monitor blood pressure, renal function, and complete blood count regularly

Hydralazine may cause lupus-like syndrome on prolonged use

Avoid alcohol and other vasodilators unless advised by the physician

Side Effects:

Common: headache, dizziness, palpitations, nausea, flushing

Less common: hypotension, fluid retention, tachycardia, lupus-like symptoms, neuropathy

Rare: angina, syncope, blood dyscrasias

Storage:

Store in a cool, dry, and dark place below 25°C
Protect from moisture and direct sunlight
Keep out of reach of children

Packaging:

Isofyle H Tablet is available in alu-alu or blister strip packs

Schedule:

Schedule H Prescription Drug – To be sold by retail on the prescription of a registered medical practitioner only

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,
Panchkula-134113

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