

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Isosorbide Dinitrate Tablets 20mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains diluted isosorbide dinitrate equivalent to 20 mg isosorbide dinitrate.

Excipients with known effect:

One tablet contains 60 mg lactose and 160 mg sucrose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablets

White round tablets marked 'IDN 20' on one side

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Prophylaxis of angina pectoris; congestive cardiac failure

4.2 Posology and method of administration

Posology

Adults and elderly patients

One or two tablets taken three or four times daily.

Paediatric population

The safety and efficacy of Isosorbide Dinitrate Tablets 20 mg has not yet been established in children.

Method of administration

For oral administration.

4.3 Contraindications

Hypersensitivity to the active substance, other nitrates or to any of the excipients.

Acute myocardial infarction with low filling pressures, acute circulatory failure (shock, vascular collapse), severe hypotension, hypertrophic obstructive cardiomyopathy (HOCM), constrictive pericarditis, cardiac tamponade, low cardiac filling pressures, aortic/mitral valve stenosis and disease associated with a raised intra-cranial pressure e.g. following a head trauma and including cerebral haemorrhage, marked anaemia, hypovolaemia.

Phosphodiesterase inhibitors (e.g. sildenafil, tadalafil and vardenafil) have been shown to potentiate the hypotensive effects of nitrates, and their co-administration with nitrates or nitric oxide donors is therefore contraindicated (see Section 4.5).

4.4 Special warnings and precautions for use

These tablets should be used with caution in patients who are suffering from hypothyroidism, hypothermia, malnutrition, angle closure glaucoma, severe hepatic or renal impairment.

Symptoms of circulatory collapse may arise after the first dose, particularly in patients with labile circulation.

This product may give rise to symptoms of postural hypotension and syncope in some patients.

Tolerance and cross-tolerance to other nitrates and nitrites may occur.

This medicine contains lactose and sucrose. Patients with rare hereditary problems of fructose intolerance, galactose intolerance, galactosaemia, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

The hypotensive effects of nitrates are potentiated by concurrent administration of phosphodiesterase inhibitors (e.g. sildenafil, tadalafil and vardenafil). This might lead to life threatening cardiovascular complications. Concurrent use is contraindicated (see Section 4.3).

Concurrent intake of drugs with blood pressure lowering properties e.g. beta-blockers, calcium antagonists, vasodilators alprostadil, aldesleukin, angiotensin II

receptor antagonists etc. and/or alcohol may potentiate the hypotensive effect of the tablets. This may also occur with neuroleptics and tricyclic antidepressants.

Symptoms of circulatory collapse can arise in patients already taking ACE inhibitors.

Nitrate preparations can act as physiological antagonists to noradrenaline, acetylcholine, histamine and other agents.

4.6 Fertility, pregnancy and lactation

Pregnancy and breast-feeding

Safety in pregnancy has not been established for isosorbide dinitrate. There is data that nitrates are excreted in breast milk and may cause methemoglobinemia in infants. Therefore, Isosorbide Dinitrate Tablets 20 mg should only be used in pregnancy and during lactation if, in the opinion of the physician, the possible benefits of treatment outweigh the hazards.

Breast-feeding

The extent of excretion of isosorbide dinitrate in human breast milk has not been determined. Therefore, caution should be exercised when administered to nursing women.

Fertility

No data on effects of fertility are available.

4.7 Effects on ability to drive and use machines

Isosorbide Dinitrate Tablets 20 mg has minor influence on the ability to drive and use machines. Headache, tiredness and dizziness may occur. Patients are advised not to drive or operate machinery if so affected.

4.8 Undesirable effects

Headache, dizziness, fatigue, palpitations, orthostatic hypotension, and flushing may occur at the beginning of treatment. These reactions are usually controlled by lowering the dose; and tend to decline with time.

Adverse reactions are listed below by system organ class and frequency. Frequencies are defined as follows: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1,000$), very rare ($< 1/100,000$), not known (cannot be estimated from the available data).

Immune system disorders

Uncommon: allergic skin reaction (e.g. rash) which may sometimes be severe.

Nervous system disorders

Very common: headache. The incidence of headache diminishes gradually with time and continued use.

Cardiac disorders

Not known: hypoxaemia. During treatment with these tablets, a temporary hypoxaemia may occur due to a relative redistribution of the blood flow in hypoventilated alveolar areas. Particularly in patients with coronary artery disease this may lead to a myocardial hypoxia.

Vascular disorders

Common: hypotension. At start of therapy or when the dosage is increased, hypotension and/or light-headedness on standing may occur. These symptoms may be associated with dizziness, drowsiness, reflex tachycardia, and a feeling of weakness.

Uncommon: flushing.

Collapse may occur (sometimes accompanied by bradyarrhythmia and syncope).

Severe hypotension may lead to enhanced angina symptoms.

Not known: severe hypotensive responses have been reported for organic nitrates and include nausea, vomiting, restlessness, pallor and excessive perspiration.

Gastrointestinal disorders and administration site conditions

Uncommon: nausea, vomiting

Not known: a few reports of heartburn, most likely due to a nitrate induced sphincter relaxation have been recorded.

Skin and subcutaneous tissue disorders

Very rare: Stevens-Johnson syndrome, angioedema

Not known: exfoliative dermatitis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdose should be treated symptomatically. Symptoms of hypotension may be treated by elevation of the legs.

If large numbers of tablets have recently been swallowed, gastric lavage may be employed.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Vasodilators used in cardiac diseases, ATC Code: CO1D A 14

Isosorbide Dinitrate produces venodilatation by relaxing the smooth muscle of the walls of the veins. Venodilatation allows blood to pool in the veins so reducing venous return to the heart. A reduced venous return improves perfusion of the myocardium. Myocardial wall tension is also reduced so the oxygen demand of the heart is decreased. Improved myocardial perfusion and reduced oxygen decrease the incidence and severity of anginal attacks.

Preload reduction is of benefit in congestive cardiac failure.

5.2 Pharmacokinetic properties

Isosorbide Dinitrate is rapidly and consistently absorbed following oral administration and exhibits dose-proportional bioavailability in the 10-120mg dosage range following single doses with the following kinetic parameters:-

T _{max} :	0.5-1 hrs
T _{1/2} Elim:	Approx 1 hr
C _{max} :	0.5-1.5ng/ml per 1mg administered

Isosorbide Dinitrate is rapidly and extensively converted to the pharmacologically active 2 and 5 Mononitrate derivatives following oral administration.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Compressible sugar
Colloidal silicon dioxide
Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Tamper evident containers composed of:
A white or grey polypropylene body, and white or grey low-density polyethylene closure.

Pack sizes: 30, 56, 60, 90, 100, 120, 180 and 240 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special precautions.

7 MARKETING AUTHORISATION HOLDER

Chemidex Pharma Limited
8a Crabtree Road
Egham
Surrey TW20 8RN
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 17736/0108

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

03/04/2009

10 DATE OF REVISION OF THE TEXT

15/02/2025