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Isosorbide Mononitrate 10/20/40mg Tablets (P)

Leaflet Size : 160 x 330 mm

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160 mm

330 mm

Pharmacode Reading Direction

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Isosorbide Mononitrate 10 mg Tablets
Isosorbide Mononitrate 20 mg Tablets
Isosorbide Mononitrate 40 mg Tablets

Isosorbide mononitrate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

1. What Isosorbide mononitrate Tablets are and what are they used for
2. What you need to know before you take Isosorbide mononitrate Tablets
3. How to take Isosorbide mononitrate Tablets
4. Possible side effects
5. How to store Isosorbide mononitrate Tablets
6. Contents of the pack and other information

1. WHAT ISOSORBIDE MONONITRATE TABLETS ARE AND WHAT ARE THEY USED FOR

Isosorbide mononitrate belongs to a group of medicines called Organic Nitrates.

Organic nitrates work by widening the blood vessels in your heart to allow an increased amount of blood to flow to areas which need it. Isosorbide mononitrate is used to prevent angina pectoris. Angina usually feels like a tight pain in the chest, neck or arm area. The pain comes from the heart muscle and is a sign that part of it is not getting enough oxygen for the amount of work it is doing.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ISOSORBIDE MONONITRATE TABLETS

Do not take Isosorbide mononitrate Tablets:
- if you are allergic (hypersensitive) to isosorbide mononitrate or any of the other ingredients in the product (see section 6)
- if you suffer from anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- if you have had a heart attack (myocardial infarction)
- if you have had a brain haemorrhage (bleeding)
- if you have had a head injury (trauma)
- if you have a low blood volume (hypovolaemia)
- if you have very low blood pressure
- if you are suffering from 'shock' as the blood has stopped circulating properly around your body (circulatory failure)
- if you take sildenafil, tadalfil or vardenafil (medicines to treat erectile dysfunction and/or pulmonary hypertension) or any other phosphodiesterase inhibitor.
- if you have an eye disease called glaucoma
- if you have been diagnosed with any of the following heart conditions: hypertrophic obstructive cardiomyopathy (HOCM), constrictive pericarditis, cardiac tamponade, low cardiac filling pressures, aortic/mitral valve stenosis and diseases associated with raised intra-cranial (head) pressure.
- if you take products that contain riociguat a medicine used in treating pulmonary hypertension.

If any of the above applies to you talk to your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before taking Isosorbide mononitrate Tablets:
- If you have an underactive thyroid gland
- If you are malnourished (severely underfed)
- If you have liver or kidney disease
- If you suffer from hypothermia (a very low body temperature)
- If you suffer from very poor circulation
- if you have abnormally low level of oxygen in the blood and impaired gas exchange due to lung disease or ischaemic heart failure.

Other medicines and Isosorbide mononitrate Tablets
Do not take Isosorbide mononitrate with phosphodiesterase inhibitors such as Sildenafil, Alprostadil, Tadalafil and Vardenafil used for impotence. Using Isosorbide mononitrate with these medicines could cause your blood pressure to fall to a dangerously low level. You must not stop taking Isosorbide mononitrate to take these medicines as this will increase your chances of having an angina attack.

Do not take Isosorbide mononitrate Tablets with products that contain riociguat.

Tell your doctor if you are taking any of the following medicines:
- Medicines to lower your blood pressure such as beta blockers (atenolol, propranolol), calcium channel blockers (nifedipine, diltiazem), vasodilators (glycerol trinitrate, methyldopa) ACE-inhibitors, angiotensin receptor blockers (olmesartan medoxomil, candesartan cilexetil) monoamine oxidase inhibitors.
- Tricyclic antidepressants such as amitriptyline, clomipramine (used to treat depression)
- Neuroleptics to treat psychosis (delusions, hallucinations and/or disordered thought) such as phenothiazines (fluphenazine) or butyrophenones (haloperidol)
- Ergotamine used for migraine.
- Aldesleukin (for kidney cancer)
- Any other medicine, including medicines obtained without a prescription.

If any of the above applies to you talk to your doctor.

Isosorbide mononitrate Tablets with food, drink and alcohol
Do not drink alcohol whilst taking this medicine. It could increase the effect of Isosorbide mononitrate and lower your blood pressure too much. If this happens, you may feel dizzy or faint.

Pregnancy, breastfeeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines
You may experience dizziness, tiredness or blurred vision when you start taking Isosorbide mononitrate Tablets. You should therefore know how you react to these tablets before you drive or use machines.

Isosorbide Mononitrate Tablets contains lactose
If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

3. HOW TO TAKE ISOSORBIDE MONONITRATE TABLETS

Always take Isosorbide mononitrate Tablets exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Important:
Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Dosage
Adults
- The usual adult dose is one tablet two or three times a day
- Your doctor will tell you when you should take your tablets. You will need to have a period of time (usually when you are sleeping) when no tablets are taken. This is called a "nitrate low" period and is needed to make sure your medicine remains effective
- Swallow the tablets whole with a drink of water after meals.
- Your doctor may increase your dose, up to a maximum of 120 mg per day.
- If you do not take the dose as prescribed by your doctor, you may develop a tolerance to Isosorbide mononitrate.

Do not use Isosorbide mononitrate to treat an actual angina attack. Your doctor will give you a different medicine such as a GTN (glyceryl trinitrate) spray or tablet for this.

Children
This medicine is not suitable for children.

If you take more Isosorbide Mononitrate Tablets than you should
Do not take more Isosorbide mononitrate than you should. If you accidentally take too much, immediately contact the nearest hospital casualty department or your doctor. Too much Isosorbide mononitrate may cause your blood pressure to fall too low, making you feel sick, faint and dizzy. A very large overdose could cause a coma or collapse and require immediate resuscitation.

If you forget to take Isosorbide Mononitrate Tablets
If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you stop taking Isosorbide Mononitrate Tablets
Do not stop taking your tablets without first discussing this with your doctor as this may be harmful.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Isosorbide mononitrate Tablets can cause side effects, although not everybody gets them.

Seek immediate medical help if you are having an allergic reaction.
This includes any of the following symptoms:
- Difficulty in breathing
- Swelling of your eyelids, face or lips
- Rash or itching especially those covering your whole body
- Collapse
- Fainting
- Exfoliative dermatitis (serious illness with red, scaly skin or blistering of the skin, mouth, eyes and genitals)

If you experience any symptoms of shock or collapse after first dose, please contact your doctor immediately.

Very common: may affect more than 1 in 10 people
- Headache (at the start of the treatment, you may have a headache. Usually this disappears after a few days)

Common: may affect up to 1 in 10 people
- Light headedness in the upright position
- Dizziness
- Drowsiness,
- Feeling weak
- Fast heart beat
- Sleepiness

They may occur for the first few days of treatment or after your dosage has been increased.

Uncommon: may affect up to 1 in 100 people
- Fainting or collapse
- Feeling sick or being sick
- Looking pale
- Worsening angina (tight pain in the chest, neck or arm area)
- Flushing.

Very rare side effects
(may affects less than 1 in 10,000 people):
- Heartburn

Not known (frequency cannot be estimated from the available data)
- Low blood pressure
- Swelling of the skin
- Excessive sweating
- Restlessness

You may also suffer with increased chest pain due to a lack of oxygen to the heart muscle and areas around the chest.
Very slow heart rate has been reported with use of nitrates.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. or by searching for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ISOSORBIDE MONONITRATE TABLETS

Keep this medicine out of the sight and reach of children.

Do not use Isosorbide mononitrate Tablets after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer needed. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Isosorbide Mononitrate Tablets contain:
The active substance is diluted isosorbide mononitrate.
- Each 10mg tablet contains diluted isosorbide mononitrate equivalent to 10mg of isosorbide mononitrate.
- Each 20mg tablet contains diluted isosorbide mononitrate equivalent to 20mg of isosorbide mononitrate.
- Each 40mg tablet contains diluted isosorbide mononitrate equivalent to 40mg of isosorbide mononitrate.

The other ingredients are:
Isosorbide mononitrate 10 mg Tablets
Microcrystalline cellulose, lactose monohydrate, colloidal silicon dioxide (E551), talc and stearic acid.

Isosorbide mononitrate 20 mg Tablets
Microcrystalline cellulose, lactose monohydrate, colloidal silicon dioxide (E551), talc and stearic acid.

Isosorbide mononitrate 40 mg Tablets
Microcrystalline cellulose, lactose monohydrate, colloidal silicon dioxide (E551), talc and stearic acid.

What Isosorbide Mononitrate Tablets looks like and contents of the pack

Isosorbide mononitrate 10 mg Tablets are white to off white circular, biconvex uncoated tablets debossed with 'I' and '10' separated by break line on one side and plain on other side.

Isosorbide mononitrate 20 mg Tablets are white to off white circular, biconvex uncoated tablets debossed with 'I' and '20' separated by break line on one side and plain on other side.

Isosorbide mononitrate 40 mg Tablets are white to off white circular, biconvex uncoated tablets debossed with 'I' and '40' separated by break line on one side and plain on other side.

The Tablets are available in PVC/aluminium blister packs of 56s for 10mg and 20mg tablets and 28s, 56s for 40mg tablets (not all pack sizes may be marketed).

Marketing Authorization Holder:
Flamingo Pharma (UK) Ltd.
1st Floor, Kirkland House, 11-15 Peterborough Road, Harrow, Middlesex, HA1 2AX, United Kingdom.

Manufacturers:
Wave Pharma Ltd.
4th Floor Cavendish House, 369 Burnt Oak Broadway, Edgware, HA8 5AW, United Kingdom.

And

Flamingo Pharma (UK) Limited
4th Floor, Cavendish House, 369 Burnt Oak Broadway, Edgware, HA8 5AW, United Kingdom

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