

VASOTRATE OD

Isosorbide Mononitrate Sustained Release Tablets 60 mg

What is in this leaflet

1. What is Vasotrate OD used for
2. How Vasotrate OD works
3. Before you use Vasotrate OD
4. How to use Vasotrate OD
5. While you are using it
6. Side effects
7. Storage and Disposal of Vasotrate OD
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Vasotrate OD is used for

Vasotrate OD is used to prevent chest pain (angina pectoris). It is not recommended for the relief of chest pain during acute attacks.

How Vasotrate OD works

Isosorbide mononitrate belongs to a group of medicines called nitrates. It works by relaxing the blood vessels, letting more blood and oxygen reach the heart.

Before you use Vasotrate OD

- When you must not use it

Do not take this medicine if you are:

- Hypersensitive to nitrates or any of the ingredients.
- Pregnant, trying to get pregnant or think you may be pregnant.
- Breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.
- Taking phosphodiesterase type 5 inhibitors, such as sildenafil, tadalafil and vardenafil.

Do not take isosorbide mononitrate if you have the following medical conditions:

- Extremely low blood pressure.
- Shock and states of collapse including those caused by low blood pressure or failing heart.
- In certain diseases of the pericardium (a double-walled sac containing the heart).
- Pericarditis (swelling around the heart).
- Weakened muscle of the heart.

Pregnancy and lactation

Do not take Vasotrate OD if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Vasotrate OD if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

You must tell your doctor if you have any of these medical conditions:

- Low blood pressure (this can make you feel faint, weak or dizzy, especially if you stand up suddenly).
- Brain damage.
- Heart disease.
- Reduced oxygen level in the blood (hypoxaemia).
- Blood deficiency (anaemia).

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Tell your doctor if you are taking any other medicines, including:

- Medicines used to treat impotence in men e.g. sildenafil, vardenafil, tadalafil.
- Medicines used to treat high blood pressure and heart conditions, such as calcium antagonists (like amlodipine), ACE inhibitors (like captopril), beta blockers, diuretics, tricyclic antidepressants (like imipramine).

How to use Vasotrate OD

- How much to use

Adults:

VASOTRATE OD 60mg (one tablet) once daily given in the morning. The dose may be increased to 120mg (two tablets) daily, both to be taken once daily in the morning. Your doctor may titrate the dose to minimise the possibility of headache, by initiating treatment with 30mg (half a tablet) for the first 2-4 day.

- When to use it

Vasotrate OD Tablets must not be chewed or crushed. They should be swallowed whole with half a glass of water.

- How long to use it

Continue taking Vasotrate OD for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. If you take too much Vasotrate OD, the following effect may happen: Pulsing headache, excitation, flushing, sweating, feeling sick (nausea), vomiting, head spinning, fainting, increase in heart rate and fall in blood pressure.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you. Tell all the doctors, dentists and pharmacists treating you that you are taking Vasotrate OD.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Vasotrate OD to anyone else, even if they have the same symptoms or condition as you.
- Do not take medicines known as phosphodiesterase type 5 inhibitor used to treat impotence (or erectile dysfunction) whilst on this medicine.

VASOTRATE OD

Isosorbide Mononitrate Sustained Release Tablets 60 mg

- *Things to be careful of*

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or drowsiness or tired do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, Vasotrate OD can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

- Low blood pressure when standing up (postural hypotension), increase in heart rate, chest pain due to obstruction in coronary arteries (angina pectoris), heart failure, high blood pressure, syncope, irregular heartbeat, slow heart rate (bradycardia), abnormal heart sound, ECG abnormal, heart attack.
- Somnolence, coughing, sensation of tingling, tickling, prickling, pricking or burning (paresthesia), insomnia (inability to get sleep or stay asleep), vertigo (feeling that you or your environment is moving or spinning), tremor, agitation, amnesia (loss of memories), impaired concentration, depression, confusion, anxiety and nervousness.
- Abdominal pain, diarrhea, flatulence, increased sweating, back pain, dyspepsia (indigestion), rhinitis (inflammation of the inside of the nose), constipation, tooth disorder, vomiting, loose stools, gastric ulcer bleeding, duodenal ulcer, dizziness, nausea, headache, fatigue, dry mouth and flushing, inflammation of the lining of the stomach.
- Rash, pruritus (itching), chronic inflammation of the skin (symptoms like dryness, redness, blistering of skin) acne (scaly red skin), abnormal hair texture, skin disorder, allergic reaction, skin nodule.
- Inflammation of the vagina, prostatic disorder, kidney stone, urinary tract infection, polyuria (excess production of urine), female breast pain, impotence,

decreased libido (low sexual desire).

- Asthenia (abnormal physical weakness or lack of energy), feeling of warmth, fever, flu-like symptoms, discomfort or uneasiness (malaise), rigors, ear ache, nose bleeding, bacterial infection, weight decrease, weight increase, peripheral edema (swelling at legs caused by abnormal accumulation of fluid in the body tissues).
- Inflammation of the gallbladder, enlarged liver, diabetes mellitus, high levels of uric acid, cerebrovascular disorder (conditions caused by problems that affect the blood supply to the brain), increase in liver enzyme.
- Conjunctivitis (itchy eyes, with discharge and crusty eyelids), double vision, abnormal vision, photophobia (extreme sensitivity to light).
- Joint pain, joint inflammation, frozen shoulder, muscle weakness, myalgia (muscle pain), inflammation of muscle, tendon disorder, musculoskeletal pain.
- Difficulty in breathing, respiratory infection, bronchitis (infection of the main airways of the lungs (bronchi), causing them to become irritated and inflamed), bronchospasm (tightening of the airways going into the lungs), inflammation of throat, pneumonia (lung infection), respiratory disorder (disorder related to respiration organ), pulmonary infiltration (deposition of substance denser than air, such as pus, blood, or protein, which lingers within the lungs), increased sputum, sinusitis and nasal congestion.
- Reduced numbers of red blood cells (anemia), reduced numbers of white blood cells (leucopenia, neutropenia, agranulocytosis), reduced numbers of platelets (thrombocytopenia), high levels of cholesterol and lipid/fat, hypocalcemia (low level of calcium in the blood).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website

portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Vasotrate OD

- *Storage*

- Keep in dry place at a temperature not exceeding 30°C, protect from light.

- *Disposal*

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

Product Description

- *What it looks like*

Light yellow coloured round biconvex, film coated tablets with breakline on one side.

- *Ingredients*

Active ingredient

- Isosorbide mononitrate.

Inactive ingredients

- Lactose.
- Hydroxypropyl methylcellulose.
- Talc.
- Magnesium stearate.
- Ethyl cellulose.
- Diethyl phthalate.
- Titanium dioxide.
- Ferric Oxide Yellow.

- *MAL number:*

MAL07061363AZ

Manufacturer

TORRENT PHARMACEUTICALS LTD.

Indrad 382 721, District: Mehsana, INDIA.

Product Registration Holder

Laboratories Torrent (Malaysia) Sdn. Bhd.

Suite E-08-08 Plaza Mont Kiara, No. 2 Jalan Kiara, Mont Kiara, 50480 Kuala Lumpur, Malaysia.

VASOTRATE OD

Isosorbide Mononitrate Sustained Release Tablets 60 mg

Date of revision

06/06/2016

Serial Number

BPFK(R4/1)110815/00239