

Trimetazidine Hydrochloride Modified Release Tablets 35mg Taj Pharma

(Trimetazidine Hydrochloride)

Package leaflet: Information for the user

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

1. Keep this leaflet. You may need to read it again.
2. If you have any further questions, ask your doctor or pharmacist.
3. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
4. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Trimetazidine is and what it is used for
2. What you need to know before you take Trimetazidine
3. How to take Trimetazidine
4. Possible side effects
5. How to store Trimetazidine
6. Contents of the pack and other information

1. What Trimetazidine 35mg is and what it is used for

This medicine is intended for use in adult patient, in combination with other medicines to treat angina pectoris (chest pain caused by coronary disease).

2. What you need to know before you take/use Trimetazidine

Do not take Trimetazidine

- if you are allergic to trimetazidine or any of the other ingredients of this medicine (listed in section 6),
- if you have a Parkinson disease: disease of the brain affecting movement (trembling, rigid posture, slow movements and a shuffling, unbalanced walk),
- if you have severe kidney problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Trimetazidine

- if you suffer from kidney problems. Your doctor may adjust the dose.

This medicine can cause or worsen symptoms such as trembling, rigid posture, slow movements and a shuffling, unbalanced walk, especially in elderly patients, which should be investigated and reported to your doctor who could reassess the treatment.

Children and adolescents

Trimetazidine is not recommended in children aged below 18 years.

Other medicines and Trimetazidine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Occurrence of interactions with other medicinal products has not been found.

Trimetazidine with food and drink

Trimetazidine can be taken irrespective of food and drink.

Pregnancy and breast-feeding

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

This medicine may make you feel dizzy and drowsy that may affect your ability to drive or use machinery.

3. How to take/use Trimetazidine

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose of Trimetazidine is one tablet to be taken two times a day during meals in the morning and evening.

If you have kidney problems or if you are older than 75 years old, your doctor may adjust the recommended dose.

Method of use

Tablets for oral use.

Please take the tablets with sufficient amount of liquid, e.g. a glass of water.

If you take more Trimetazidine than you should

No cases of occurrence of poisoning by the medicinal product owing to an overdose has been reported.

If you forget to take Trimetazidine

Do not take a double dose to make up for a forgotten tablet/dose.

If you stop taking Trimetazidine

Do not stop taking your medicine without consulting your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Common (may affect up to 1 in 10 people):

Dizziness, headache, abdominal pain, diarrhoea, indigestion, feeling sick, vomiting, rash, itching, hives and feeling of weakness.

Rare (may affect up to 1 in 1,000 people):

Fast or irregular heartbeats (also called palpitations), extra heartbeats, faster heartbeat, fall in blood pressure on standing-up which causes dizziness, light headedness or fainting, malaise (generally feeling unwell), dizziness, fall, flushing.

Not known (frequency cannot be estimated from the available data):

Extrapyramidal symptoms (unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs), usually reversible after treatment discontinuation.

Sleep disorders (difficulty in sleeping, drowsiness), constipation, serious generalised red skin rash with blistering, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

Severe reduction in number of white blood cells which makes infections more likely, reduction in blood platelets, which increases risk of bleeding or bruising.

A liver disease (nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine).

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Trimetazidine

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

Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.



Do not store above 30 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Trimetazidine contains

Each film coated modified-release tablet contains:

Trimetazidine hydrochloride BP 35mg

Excipients q.s.

Colour: Tartrazine

Nature and contents of container

Blisters (PVC/aluminium) in packs of 7, 14, 28, 30, 50, 100 and 500 modified release tablets.

Not all pack sizes may be marketed.

7. Manufactured In India By:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

Unit No. 214.Old Bake House,

Maharashtra chambers of Commerce Lane,

Fort, Mumbai - 400001

at:Gujarat, INDIA.

Customer Service and Product Inquiries:

1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00 p.m.

EST

E-mail: tajgroup@tajpharma.com