

AXI-NOVELL 35 mg MR Tablet

Trimetazidine Dihydrochloride

Consumer Medicine Information Leaflet (RiMUP)

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What AXI-NOVELL 35mg MR Tablet is used for

OTHER CARDIAC PREPARATIONS - ATC code: C01EB15

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

How AXI-NOVELL 35mg MR Tablet works

Trimetazidine acts by inhibiting the breakdown of fatty acids which enhances glucose oxidation. Energy obtained during glucose oxidation requires less oxygen consumption thus optimises the heart's energy producing function, protecting vulnerable heart muscle tissue from further oxygen-deprived damage.

Before you use AXI-NOVELL 35mg MR Tablet

- When you must not use it

Do not take AXI-NOVELL 35mg MR Tablet:

- if you are allergic to trimetazidine or any of the other ingredients of this medicine
- 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

- Before you start to use it

Talk to your doctor or pharmacist before taking AXI-NOVELL 35mg MR Tablet.

This medicinal product is not a curative treatment for angina attacks, nor an initial treatment for unstable angina. It is not a treatment for myocardial infarction.

In the event of chest pain angina attack, inform your doctor. Tests may be required and your treatment may possibly be modified. 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.

This medicinal product is generally not recommended during breastfeeding.

Falls may occur following a drop in blood pressure or a loss of balance (see description of side effects).

Children and adolescents

AXI-NOVELL 35mg MR Tablet is not recommended in children aged below 18 years.

- Taking other medicines

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

How to use AXI-NOVELL 35mg MR Tablet

Always take AXI-NOVELL 35mg MR Tablet exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. AXI-NOVELL 35mg MR Tablet is to be taken orally.

- How much to use

The recommended dose of AXI-NOVELL 35mg MR Tablet 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.

- When to use it

The tablets should be swallowed with a glass of water at mealtimes.

- How long to use it

ALWAYS USE EXACTLY AS INDICATED IN YOUR DOCTOR'S PRESCRIPTION.

- If you forget to use it

Resume treatment normally. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

Consult a doctor or a pharmacist immediately.

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 AXI-NOVELL 35mg MR Tablet.

It is preferable not to take this medicine during pregnancy. If you discover that you are pregnant whilst taking this medicine, consult your doctor as he alone can judge the necessity of continuing your treatment.

- 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 AXI-NOVELL 35mg MR Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Pregnancy and breastfeeding

Pregnancy

It is preferable not to use this medicine during pregnancy. If you discover that you are pregnant whilst taking this medicine, consult your doctor.

Breastfeeding

AXI-NOVELL 35mg MR Tablet is not recommended to be used while breastfeeding.

If you are pregnant or breastfeeding, or think that you may be pregnant or

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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.

Side Effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects have been described:

Common side effects:

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

Rare side effects:

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

Other side effects:

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), dizziness, 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.

Liver disease (nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured stools, 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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of AXI-NOVELL 35mg MR Tablet

- Storage

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

Do not use this medicine after the expiry date which is stated on the packaging.

Store below 30°C.

- Disposal

Do not throw away any medicines 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:

Red, round, convex film coated tablet, plain on both sides

- Ingredients

- Active ingredient: Trimetazidine dihydrochloride.
One modified-release film-coated tablet contains 35 mg of Trimetazidine dihydrochloride.
- Inactive ingredients: Hydroxyl Propyl Methyl Cellulose, Calcium Hydrogen Phosphate Dihydrate, Colloidal Silica Anhydrous, Magnesium Stearate, Ethylene Glycol and Vinyl Alcohol Graft Copolymer combined with Polyvinyl Alcohol, Titanium Dioxide, Talc, and Iron Oxide Red

- MAL number:

MAL23036149AZ

Manufacturer

PT. Novell Pharmaceutical Laboratories

Jl. Wanaherang No. 35, Tlajung Udik, Gunung Putri, Bogor 16962 – Indonesia

Product Registration Holder

Celestema Pharma Sdn. Bhd.
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Date of Revision

24/03/2025

Serial Number

NPRA (R2) 21/134