

# MIANSERIN-REMEDICA FILM COATED TABLETS

Mianserin Hydrochloride (10mg, 30mg)

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**What Mianserin-Remedica is used for**

Mianserin are used to treat the symptoms of depression particularly with anxiety.

**How Mianserin-Remedica works**

Mianserin belongs to a group of medicines called tetra-cyclic antidepressants. Mianserin is believed to work by increasing the levels of two naturally occurring chemicals within the brain, noradrenaline and 5 hydroxytryptamine (also called serotonin).

**Before you use Mianserin-Remedica****- When you must not use it**

- you are allergic to mianserin or any other ingredients of this medicine (listed in Product Description).
- Suffer from severe liver disease.
- Have mania (feeling over-excited with unusual behaviour).
- Breast-feeding
- Are pregnant

**- Before you start to use it**

Talk to your doctor or pharmacist before taking mianserin if you:

- Have ever had an epileptic seizure (a fit) or are at risk of having one due to any of the following reasons:
  - Are recovering from a recent heart attack (myocardial

infarction) or suffer from a condition known as heart block.

- Are diabetic
- Have kidney or other liver problems
- Enlarged prostate gland.

This medicine might increase the risk of suicidal thinking and behaviour in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders.

Therefore, the families and caregivers for patient with MDD should be advised to closely observe patient and inform the doctor if they notice any unusual changes in behaviour, suicidality or worsening of patient's condition.

These products contain Lactose, so patients with galactose intolerance (inability to break down galactose) should not take this medicine.

**- Taking other medicines**

Do not take Mianserin if you are taking:

- A monoamine oxidase inhibitor (MAOI). You should not take mianserin at the same time or within 2 weeks of taking an MAOI. If you have taken mianserin, you should wait 1-2 weeks before you take a MAOI.

**How to use Mianserin-Remedica****- How much to use**

Mianserin-Remedica is given orally in doses of 30 mg daily for the first few days. The effective daily dosage is usually between 30 mg and 90 mg. The recommended initial daily dose in the elderly is not more than 30 mg, which may be slowly increased if necessary.

The medicine is not recommended for use in children.

**- When to use it**

The daily dosage may be divided throughout the day or given as a single dose at night.

**- How long to use it**

You should take your tablets for as long as your doctor says. Do not stop taking this medicine just because you do think that it is not working. You may need to take these tablets for a long time.

Your dose will be adjusted so that it is right for you and helps control the symptoms of your illness.

**- If you forget to use it**

Take the next dose as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

**- If you use too much (overdose)**

Contact your doctor immediately or go to the Emergency Department of your nearest hospital. Take the container and any remaining tablets with you.

You may have the following symptoms: prolonged sedation, irregular heartbeat, convulsions, severe low blood pressure and breathing difficulties.

**While you are using it****- Things you must do**

Tell all the doctors, dentists and pharmacists treating you that you are using Mianserin-Remedica.

**- Things you must not do**

Do not take Mianserin-Remedica for longer than your doctor has prescribed.

Do not stop taking Mianserin-Remedica or change the dose without checking with your doctor.

Do not take Mianserin-Remedica to treat any other condition unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Do not drive or operate machinery because this medicine may make you feel drowsy. Alcohol can make the feeling of drowsiness worse.

**Side effects**

Like all medicines, Mianserin-Remedica can cause side effects, although not everybody gets them.

If you begin to experience any of the following side effects stop taking Mianserin and contact your doctor immediately:

- Sore throat, mouth ulcers, cold sores, or other infections, inflammation of the mouth lining, fever, feeling tired, weak or pale. These may be signs of changes in the numbers of certain blood cells which may indicate a problem with the bone marrow (where these cells are produced), more common in elderly patients.
- Thoughts of harming or killing yourself, or behaviours consistent with trying to harm or kill yourself.
- Fits (convulsions)
- Yellowing of the skin or whites of the eyes

Other possible side effects include:

- Breast enlargement in men
- Nipple tenderness
- Production of breast milk (in men, or in women who are not expecting to produce milk)
- Disturbances of liver function
- Joint pain and swollen joints.
- Dizziness, light-headedness or fainting on standing up (these may be a sign of low blood pressure).
- Fluid retention
- Skin rash
- Sweating
- Shaking

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

**Storage and Disposal of Mianserin-Remedica**

- Storage

Keep this medicine out of sight and reach of children.

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

Store below 30°C. Protect from light and moisture.

- 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

*Mianserin-Remedica 10 mg film-coated tablets:*  
White, round, film-coated tablets.

*Mianserin-Remedica 30 mg film-coated tablets:*  
White, round, film-coated tablets.

- Ingredients

- Active ingredient(s)  
The active ingredient is mianserin hydrochloride.

- Inactive ingredients  
The other ingredients are:

*Mianserin-Remedica 10 mg film-coated tablets:*

Microcrystalline cellulose, pregelatinised starch, povidone, lactose monohydrate, maize starch, colloidal anhydrous silica, magnesium stearate, talc, hypromellose, macrogol 400, titanium dioxide.

*Mianserin-Remedica 30 mg film-coated tablets:*

Microcrystalline cellulose, sodium starch glycolate (Type A), lactose monohydrate, maize starch, povidone, colloidal anhydrous silica, magnesium stearate, talc, hypromellose, macrogol 400, titanium dioxide.

- MAL number(s):

*Mianserin-Remedica 10 mg film-coated tablets:*  
MAL19920636AZ

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MAL19920635AZ

**Manufacturer**

Remedica Ltd,  
Aharnon Str.,  
Limassol Industrial Estate,  
3056 Limassol, Cyprus

**Product Registration Holder**

Eucogen Sdn. Bhd.,  
No. 6A, Jalan Sungai Burung U 32/U,  
Bukit Rimau, Seksyen 32, 40460  
Shah Alam.

**Date of revision**

11/04/2023

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