

MITAPINE 15

MITAPINE 30

Mirtazapine Tablet (15mg & 30mg)

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What MITAPINE is used for

MITAPINE is indicated for use in patients with major depression.

How MITAPINE works

Mirtazapine which is the active ingredient of MITAPINE works by enhancing neurotransmission in the brain and therefore contributing to antidepressant activity.

Before you use MITAPINE

- When you must not use it

Do not use MITAPINE if you are allergic to the active substance or any of its excipients listed in this leaflet.

Do not use this product if you are taking other medications called monoamine oxidase (MAO) inhibitors.

MITAPINE is not recommended for use in patients below the age of 18 years.

- Before you start to use it

Tell your doctor if:

- You are allergic to any of the ingredients used in this product.
- You are pregnant, planning to start a family or breastfeeding.

If you have any of the following medical conditions, please inform your doctor before taking this

medication:

- Thoughts of suicide or self-harm.
- Epilepsy (fits or convulsions).
- Liver disease such as jaundice.
- Kidney disease.
- Heart disease.
- Low blood pressure.
- Any other mental illness (e.g. schizophrenia, manic depression).
- Diabetes.
- Glaucoma (increased pressure in eye).
- Problems urinating due to enlarged prostate.
- Unexplained high fever, sore throat and mouth ulcers.
- Lactose intolerance.
- Phenylketonuria.

- Taking other medicines

Inform your doctor or pharmacist if you are taking any other medications including those purchased without a prescription from the pharmacy or from a health-food shop before starting this medication.

MITAPINE is not recommended to be used alongside medications known as monoamine oxidase (MAO) inhibitors.

Close monitoring should be done by your doctor if you are taking other medications as listed below:

- Other antidepressants.
- Sedatives.
- Blood thinners such as warfarin.
- Anti-epileptic drugs such as carbamazepine.
- Anti-fungal medication such as ketoconazole.
- Anti-retroviral drugs.
- Medication for stomach acidity such as cimetidine.

If you are not sure what medications you are currently on, please check with your doctor or pharmacist.

How to use MITAPINE

- How much to use

Treatment with MITAPINE usually starts with 15mg once a day. Your doctor may increase the dose based on your response. An effective daily dose is usually between 15mg and 45mg once a day, decided by your doctor.

- When to use it

You are advised to take MITAPINE at night unless advised differently by your doctor.

- How long to use it

Continue taking MITAPINE for as long as your doctor recommends.

You will generally start to feel the effectiveness of this medication after 1 to 2 weeks of taking it. Full effects of this medication is generally felt after 2 to 4 weeks of treatment.

Do not stop taking this medication unless it has been advised by your doctor.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to take this medication. Do not double up the dose to make up for a missed dose as this will put you at risk of overdose.

- If you use too much (overdose)

Contact your doctor or visit the emergency department of the nearest hospital immediately if you have overdosed or suspected you may have overdosed on this medication.

While you are using MITAPINE

- Things you must do

Tell your doctor immediately if you

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Mirtazapine Tablet (15mg & 30mg)

develop fever, chills, sore throat, mouth ulcers or other signs of frequent infections. MITAPINE can possibly depress your immune system however, this effect is reversible.

Inform your doctor immediately if you have thoughts of suicide or if you depression becomes worse while on MITAPINE.

Before starting any new medication, tell your doctor, pharmacist or dentist that you are on MITAPINE.

- Things you must not do

Driving and operating heavy machinery is not recommended while on MITAPINE. This medication may impair your concentration and alertness by causing drowsiness.

Do not stop taking this medication or change the dose without seeking advice from your doctor first.

Do not share this medication with anyone else even if they display the same symptoms as you. This medication has been specially prescribed for you only.

- Things to be careful of

You are advised to be cautious if you consume alcohol while on MITAPINE. Alcohol can enhance the drowsy effects of this medication.

Your doctor may advise you to stop taking alcohol while on this medication.

Side effects

Like other medications, MITAPINE can cause side effects although not everyone will experience them. Inform your doctor if you experience any side effects, including those that is not listed in this leaflet. Some very common and common side effects are as follows:

Very common: increase in appetite, weight gain, sedation, headache and dry mouth.

Common: abnormal dreams, confusion, anxiety, insomnia, lethargy, dizziness, tremors, low blood pressure, nausea, diarrhoea, vomiting, constipation, body aches and pains, swelling and skin rashes, memory problems.

Not known: Serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature and enlarged lymph nodes.

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 MITAPINE

- Storage

Do not store above 30°C. Protect from light and moisture. Keep out of reach of children.

- Disposal

Do not dispose unwanted or expired medication via water or household waste. These measures will help protect the environment from pollution. Seek advice from your pharmacist on proper medication disposal steps.

Product Description

- What it looks like

MITAPINE 15

Yellow to light yellow, biconvex, oval shaped, scored, film coated tablets debossed with "M" & "5" on either side of break line on one side and plain on other side.

MITAPINE 30

Reddish brown, biconvex, oval shaped, scored, film coated tablets debossed with "M" & "6" on either side of break line on one side and plain on other side.

- Ingredients

Active Ingredient(s)

Mirtazapine

Inactive ingredients

MITAPINE 15: Maize starch, lactose monohydrate, hydroxypropyl cellulose, colloidal anhydrous silica, magnesium stearate, opadry yellow 03F520551, purified water.

MITAPINE 30: Maize starch, lactose monohydrate, hydroxypropyl cellulose, colloidal anhydrous silica, magnesium stearate, opadry beige 03F570104, purified water.

- MAL number(s)

MITAPINE 15: MALXXXAZ

MITAPINE 30: MALXXXAZ

Manufacturer

Unison Pharmaceuticals Pvt Ltd
Unit-III, C-7,8,9, Steel Town, Opp. Nova Petrochemicals, Village Moraiya, Sanand, Ahmedabad, Gujarat 382213, India.

Product Registration Holder

Celestemal Pharma Sdn Bhd
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Date of revision

21/01/2026

Serial Number

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