

MENELAT TABLETS

Mirtazapine (30 mg, 45 mg)

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What Menelat is used for

- Mirtazapine is one of a group of medicines called antidepressants.
- Menelat Tablets are used to treat major depressive illness.

How Menelat works

Mirtazapine works in the brain to block receptors and corrects the chemical imbalance in the brain which leads to antidepressant effects.

Before you use Menelat

- When you must not use it

Do not take Menelat:

- If you are allergic (hypersensitive) to mirtazapine or any of the other ingredients of Menelat Tablets. If so, you must talk to your doctor as soon as you can before taking Menelat Tablets.
- If you are taking or have recently taken (within the last two weeks) medicines called monoamine oxidase inhibitors (MAO-Is).

Pregnancy and lactation

Do not take Menelat if you are pregnant or plan to become pregnant or think you might be pregnant.

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

- Before you start use it

Tell your doctor about these conditions before taking Menelat Tablets:

- Seizures (epilepsy). If you develop seizures or your seizures become more frequent, stop taking Menelat Tablets and contact your doctor immediately.
- Liver disease, including jaundice. If jaundice occurs, stop taking

Menelat Tablets and contact your doctor immediately.

- Taking other medicines

Tell your doctor or pharmacist if you are taking (or plan to take) any of the medicines in the following list.

Please also tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not take Mirtazapine Tablets in combination with:

- Monoamine oxidase inhibitors (MAO inhibitors). Also, do not take Menelat Tablets during the two weeks after you have stopped taking MAO inhibitors. If you stop taking Menelat Tablets, do not take MAO inhibitors during the next two weeks either. Examples of MAO inhibitors are moclobemide, tranylcypromine (both are antidepressants) and selegiline (used for Parkinson's disease).

Take care when taking Menelat Tablets in combination with:

- Antidepressants such as SSRIs, venlafaxine and L-tryptophan or triptans (used to treat migraine), tramadol (a pain-killer), linezolid (an antibiotic), lithium (used to treat some psychiatric conditions) and St. John's Wort – *Hypericum perforatum* preparations (a herbal remedy for depression). In very rare cases Menelat Tablets alone or the combination of Menelat Tablets with these medicines, can lead to a so-called serotonin syndrome. Some of the symptoms of this syndrome are: inexplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes and unconsciousness. If you get a combination of these symptoms, talk to your doctor immediately.
- The antidepressant nefazodone. It can increase the amount of mirtazapine in your blood. Inform your doctor if you are using this medicine. It might be necessary to lower the dose of Menelat Tablets, or when use of nefazodone is

stopped, to increase the dose of Menelat Tablets again.

- Medicines for anxiety or insomnia (difficulty to sleep) such as benzodiazepines.
- Medicines for infections; medicines for bacterial infections (such as erythromycin, medicines for fungal infections (such as ketoconazole) and medicines for HIV/AIDS (such as HIV-protease inhibitors). In combination with Menelat Tablets these medicines can increase the amount of mirtazapine in your blood. Inform your doctor if you are using these medicines. It might be necessary to lower the dose of Menelat Tablets, or when these medicines are stopped, to increase the dose of Menelat Tablets again.
- Medicines for epilepsy such as carbamazepine and phenytoin;
- Medicines for tuberculosis such as rifampicin.
- In case of diabetes (you may need to adjust your dose of insulin or other antidiabetic medicines).

How to use Menelat

- How much to use

The usual starting dose is 15 mg daily

Your doctor may advise you to increase your dose after a few days to the amount that is best for you (between 15 and 45 mg per day). Mirtazapine should not be used in children and adolescents under 18 years of age.

However, if you are an elderly person or if you have kidney or liver disease, your doctor may prescribe a lower dose.

- When to use it

Take Menelat Tablets at the same time each day. It is best to take Menelat Tablets as a single dose before you go to bed. However your doctor may suggest you to split your dose of Menelat Tablets – once in the morning and once at night-time before you go to bed. The higher dose should be taken before you go to bed. Take your tablets orally. Swallow your prescribed dose of Menelat Tablets without chewing, with some water or juice.

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- How long to use it

Continue taking Mirtazapine for as long as your doctor recommends.

Always take this medicine exactly as your doctor has told you. This will help you to get the best results and lower the risk of side effects. You should check with your doctor or pharmacist if you are not sure.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use Menelat.

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. Taking too many tablets may cause depression, increase in heart rate and increase or decrease 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 that are treating you that you are taking Mirtazapine.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Mirtazapine can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how Mirtazapine affects you.
- Avoid drinking alcohol or taking diazepam (a medicine used for anxiety, insomnia and seizures, for example) or similar medicines while taking Mirtazapine. If you are uncertain about whether certain medication can be taken with

Mirtazapine, please discuss with your doctor.

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Mirtazapine to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Be careful when drinking alcohol while taking Mirtazapine.

Combining Mirtazapine and alcohol can make you sleepier and less alert. Your doctor may suggest you avoid alcohol while being treated with this medicine.

Side effects

Tell your doctor and stop taking mirtazapine immediately if you notice any of the following side effects:

Very Common:

- Increase in appetite and weight gain.
- Drowsiness or sleepiness.
- Headache.
- Dry mouth.

Common:

- Abnormal dreams.
- Confusion.
- Anxiety.
- Insomnia (difficult to sleep).
- Lethargy.
- Dizziness.
- Tremor.
- Orthostatic hypotension (occurs when a person's blood pressure falls when suddenly standing up from a lying or sitting position).
- Nausea.
- Diarrhea.
- Vomiting.
- Exanthema (a skin rash accompanying a disease or fever).
- Arthralgia (joint pain).
- Myalgia (muscle pain).
- Back pain.
- Oedema peripheral (swelling usually in the lower limbs).
- Fatigue.
- Memory problems.

Frequency '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.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the side effects of mirtazapine. For more information, ask your healthcare provider or pharmacist.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Menelat

- Storage

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

- 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

MENELAT 30 MG TABLETS

Pink coloured, round, biconvex film coated tablets plain on one side and breakline on other side.

MENELAT 45 MG TABLETS

White to off white coloured, round, biconvex film coated tablets plain on both sides.

Ingredients

Active ingredient

- Mirtazapine.

Inactive ingredients

- Lactose monohydrate.

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- Maize starch.
- Low-substituted hydroxy propyl cellulose.
- Hydroxy propyl cellulose.
- Colloidal silicon dioxide (Aerosil 200).
- Magnesium Stearate.
- Hypromellose 2910 (6 cps).
- HPMC 2910 E15 LV (Hypromellose).
- Polyethylene Glycol 6000.
- Titanium dioxide.
- Ferric oxide red (Menelat 30 mg).

- MAL number(s):

MENELAT 30 MG TABLETS:

MAL17075013AZ

MENELAT 45 MG TABLETS:

MAL17075015AZ

Manufacturer

TORRENT PHARMACEUTICALS
LTD.
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INDIA.

Product Registration Holder

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Date of revision

22/09/2021

Serial Number

NPRA(R2/1)210906/739