

AUROZAPINE 15

AUROZAPINE 30

Mirtazapine Tablet (15mg & 30mg)

What is in this leaflet

1. What AUROZAPINE is used for
2. How AUROZAPINE works
3. Before you use AUROZAPINE
4. How to use AUROZAPINE
5. While you are using it
6. Side effects
7. Storage and Disposal of AUROZAPINE
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What is AUROZAPINE used for

AUROZAPINE is indicated for use in patients with major depression.

How AUROZAPINE works

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

Before you use AUROZAPINE

-When you must not use it

Do not use AUROZAPINE 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.

AUROZAPINE 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 medications

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.

AUROZAPINE 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 AUROZAPINE

-How much to use

Treatment with AUROZAPINE 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 AUROZAPINE at night unless advised differently by your doctor.

-How long to use it

Continue taking AUROZAPINE 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.

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While you are using it

-Things you must do

Tell your doctor immediately if you develop fever, chills, sore throat, mouth ulcers or other signs of frequent infections. AUROZAPINE 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 AUROZAPINE.

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

-Things you must not do

Driving and operating heavy machinery is not recommended while on AUROZAPINE. 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 AUROZAPINE. 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, AUROZAPINE can cause side effects although not everyone will experience them. Inform your doctor if you experience any side effects, including those that are 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 effect 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 product name

-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

AUROZAPINE 15: yellow, biconvex capsule shaped film coated tablets with a score-line in between 0 and 8 on one side and 'A' debossed on the

other side.

AUROZAPINE 30: reddish brown, biconvex capsule shaped film coated tablets with a score-line in between 0 and 9 on one side and 'A' debossed on the other side.

-Ingredients

· Active ingredient(s)

Mirtazapine

· Inactive ingredient(s)

AUROZAPINE 15: Low substituted hydroxypropylcellulose, hydroxyl propyl cellulose, purified water, maize starch, colloidal anhydrous silica, magnesium stearate, purified water, lactose monohydrate, opadry yellow.

AUROZAPINE 30: Low substituted hydroxypropylcellulose, hydroxyl propyl cellulose, purified water, maize starch, colloidal anhydrous silica, magnesium stearate, purified water, lactose monohydrate, opadry brown.

-MAL number

AUROZAPINE 15: MAL18086119AZ
AUROZAPINE 30: MAL18086140AZ

Manufacturer

Aurobindo Pharma Limited
Unit-III, Survey no.: 313, 314
Bachupally, Bachupally Mandal,
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Product Registration Holder

Healol Pharmaceutical Sdn. Bhd.

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Date of revision

-15/04/2023

Serial Number

NPRA(R2/1)211213/805