

AUROZAPINE™ 15, 30 & 45

Mirtazapine film-coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions people ask about AUROZAPINE. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking AUROZAPINE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What AUROZAPINE is used for

AUROZAPINE is used in the treatment of depression including relapse prevention.

Depression is longer lasting or more severe than "low moods" everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

This medicine corrects this chemical imbalance and may help relieve the symptoms of depression.

Your doctor, however, may prescribe it for another purpose.

You must follow all the directions given to you by your doctor. They can differ from the information in this leaflet.

Always ask your doctor if you need more information.

AUROZAPINE is not addictive.

AUROZAPINE is only available with a doctor's prescription.

Before you take it

When you must not take it

Do not take AUROZAPINE:

- if you are allergic to medicines containing mirtazapine; or
- if you are allergic to any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing.

Do not take AUROZAPINE if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking an MAOI within the last 14 days. If you stop taking AUROZAPINE, do not take MAOIs during the next two weeks either.

Taking AUROZAPINE with an MAOI may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Examples of this type of medicine include phenelzine, tranylcypromine and selegiline.

Ask your doctor or pharmacist if you are not sure if you are or if you have been taking a MAOI medicine.

Do not take AUROZAPINE after the use by (expiry date) printed on the pack has passed.

It may have no effect at all or an unexpected effect if you take it after the expiry date.

Do not take AUROZAPINE if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

If you are not sure whether you should start taking AUROZAPINE, talk to your doctor.

Before you start to take it

Do not give AUROZAPINE to a child or adolescent.

The safety of AUROZAPINE in patients under 18 years has not been established.

Tell your doctor if:

1. **you are allergic to any other medicines, foods, dyes or preservatives;**
2. **you are pregnant or plan to become pregnant.**
Like most medicines of this kind, AUROZAPINE is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of taking AUROZAPINE when pregnant.
3. **you are breastfeeding or wish to breastfeed.**
It is not known whether AUROZAPINE passes into breast milk.
4. **if you have or have had any medical conditions, especially the following:**
 - thoughts of suicide or self-harm;
 - epilepsy (fits or convulsions);
 - liver disease such as jaundice;
 - kidney disease;
 - heart disease;
 - low blood pressure;
 - certain kinds of heart conditions that may change your heart rhythm, a recent heart attack, heart failure, or take certain medicines that may affect the heart's rhythm;
 - any mental illness (e.g. schizophrenia, manic depression);
 - diabetes;
 - glaucoma (increased pressure in the eye);
 - problems in urinating due to an enlarged prostate;
 - unexplainable high fever, sore throat and mouth ulcers;
 - galactose intolerance; or
 - glucose-galactose malabsorption.

If you have not told your doctor about any of the above, tell them before you take AUROZAPINE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your

pharmacy, supermarket or health food shop.

Some medicines may be affected by AUROZAPINE or may affect how well it works. These include:

- other medicines (e.g. SSRIs, venlafaxine, L-tryptophan, nefazodone) for depression, anxiety, obsessive compulsive disorders or pre-menstrual dysphoric disorder;
- Monoamine Oxidase Inhibitors (such as tranylcypromine, phenelzine, and selegiline);
- medicines containing St. John's Wort (*Hypericum perforatum*);
- phenytoin or carbamazepine, medicines used to treat epilepsy;
- benzodiazepines, medicines used to treat anxiety and sleeping problems;
- lithium, a medicine used to treat some psychiatric conditions;
- methylene blue (used to treat high levels of methemoglobin in the blood);
- tramadol, a pain killer;
- morphine, a medicine for severe pain;
- cetirizine, a medicine for allergies;
- warfarin, a medicine used to prevent blood clotting;
- linezolid or erythromycin, both antibiotics;
- rifampicin, a medicine used to treat tuberculosis;
- medicines used to treat fungal infections such as ketoconazole;
- HIV/AIDS medications;
- cimetidine, a medicine used to treat reflux and stomach ulcers;
- triptans such as sumatriptan, naratriptan and zolmitriptan, medicines used to treat migraine; or
- medicines that may affect the heart's rhythm such as certain antibiotics and some antipsychotics.

Your doctor will tell you what to do if you are taking any of these medicines.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. If you have not told your doctor about any of these things, tell them before you take any AUROZAPINE.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

How to take it

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

Your doctor will tell you how much AUROZAPINE to take each day. Take exactly the amount your doctor tells you.

The usual starting dose is 15 mg per day. Your doctor may slowly increase this dose depending on how you respond to AUROZAPINE. The effective dose for most people is usually between 30 mg and 45 mg per day.

Your doctor may have prescribed a different dose.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How and when to take it

Take AUROZAPINE at about the same time each day.

Your doctor will tell you when to take your tablets.

The tablet(s) should be taken at the same time each day, preferably as a single night-time dose before going to bed; if recommended by your doctor, AUROZAPINE may be taken in sub-doses equally divided over the day (once in the morning and once at night-time before going to bed).

Swallow the tablet(s), without chewing, together with some water or other fluid.

How long to take it

Keep taking AUROZAPINE until your doctor tells you to stop.

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so do not be discouraged if you don't feel better right away. Some of your symptoms may improve in 1 to 2 weeks but it can take up to 2 – 4 weeks to feel the full benefit of the medicine.

Even when you feel well, you will usually have to take AUROZAPINE for 4 to 6 months or even longer to make sure the benefits will last.

If you forget to take it

ONCE DAILY DOSING

If you forget to take the tablet before you go to bed, do not take the missed dose next morning. It may cause drowsiness or sleepiness during the day. Continue treatment in the evening with your normal dose.

TWICE DAILY DOSING

- **Morning dose forgotten – simply take it together with your evening dose;**
- **Evening dose forgotten - do not take it with the next morning dose. Continue treatment with your normal morning and evening doses; or**
- **Both doses forgotten - do not try to make up for the missed tablets. Continue with your usual morning and evening dose the next day.**

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much AUROZAPINE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many AUROZAPINE tablets, you may feel drowsy, dizzy, confused and agitated. You may also have changes to your heart rhythm (fast, irregular heartbeat) and/or fainting which could be symptoms of

a life-threatening condition known as Torsade de Pointes.

While you are taking it

Things you must do

Tell your doctor immediately if you develop fever, chills, sore throat or mouth ulcers or other signs of frequent infections. Stop taking AUROZAPINE and consult with your doctor for a blood test.

In rare cases mirtazapine can cause disturbances in the production of blood cells (bone marrow depression). Some people become less resistant to infection because AUROZAPINE can cause a temporary shortage of white blood cells (granulocytopenia). In rare cases AUROZAPINE can also cause a shortage of white blood cells, as well as blood platelets (aplastic anemia), a shortage of blood platelets (thrombocytopenia) or an increase in the number of white blood cells (eosinophilia). While rare, these symptoms most commonly appear after 4 - 6 weeks of treatment.

Tell your doctor immediately or go to the nearest hospital for treatment if you have any suicidal thoughts or other mental/mood changes.

Occasionally, the symptoms of depression or other psychiatric conditions may include thoughts of harming yourself or committing suicide. Until the full antidepressant effect of your medicine becomes apparent, it is possible these symptoms may increase in the first few weeks of treatment.

Information from clinical trials has shown an increased risk of suicidal behaviour in young adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you or someone you know is showing warning signs of suicide-related behaviour while taking AUROZAPINE, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment. These signs include:

- thoughts or talk about death or suicide;
- thoughts or talk of self-harm or harm to others;
- any recent attempts of self-harm; or
- increase in aggressive behaviour, irritability or agitation.

All mentions of suicide or violence must be taken seriously.

You may find it helpful to tell a relative or close friend that you are depressed, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Tell your doctor if you become pregnant while taking this medicine. Do not stop taking your tablets until you have spoken to your doctor.

If you use AUROZAPINE until, or shortly before birth, your baby should be supervised for possible adverse effects.

Ask your doctor whether you can breast-feed, while taking AUROZAPINE.

Tell your doctor if for any reason you have not taken your medicine exactly as prescribed.

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the tablets are not helping your condition.

Be sure to keep all of your appointments with your doctor so that your progress can be checked.

You may need to have blood tests from time to time.

Tell all doctors, dentists and pharmacists who are treating you that you are taking AUROZAPINE.

If you are about to be started on new medicine, tell your doctor, dentist or pharmacist that you are taking AUROZAPINE.

If you go into hospital, please let the medical staff know you are taking AUROZAPINE.

Things you must not do

Do not drive or operate machinery until you know how AUROZAPINE affects you.

AUROZAPINE may cause drowsiness, dizziness or sleepiness in some people and affect alertness and concentration. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Do not suddenly stop taking AUROZAPINE, or lower the dose, without first checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not stop taking AUROZAPINE, or lower the dosage, without checking with your doctor.

Suddenly stopping AUROZAPINE may cause nausea, headache, dizziness, anxiety and agitation.

Your doctor may want to gradually reduce the amount of AUROZAPINE you are taking before stopping completely.

Do not give AUROZAPINE to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.

Do not take AUROZAPINE to treat any other conditions unless your doctor tells you to.

Things to be careful of

You are advised not to drink any alcohol while taking AUROZAPINE.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AUROZAPINE.

AUROZAPINE helps most people with depression, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Tell your doctor if you notice any of the following and they bother you:

- lethargy, drowsiness or sleepiness;
- headache;
- tiredness;
- increase in appetite and weight gain;
- dry mouth;
- nausea, vomiting;
- diarrhoea;
- constipation;
- dizziness;
- dizziness or faintness, especially when getting up quickly from a lying or sitting position (low blood pressure);
- abnormal sensations in the mouth, sensations of numbness in the mouth or swelling in the mouth;
- aggression;
- swollen ankles or feet as a result of fluid accumulation (oedema);
- rash or skin eruptions;
- nightmares/vivid dreams;
- tingling fingers or toes;
- painful joints;
- back pain;
- muscle aches and pains;
- restless legs;
- abnormal sensation in the skin for example burning, stinging, tickling or tingling;
- urge to move;
- speech disorders;
- difficulty in passing urine (urinary retention); or
- anxiety, insomnia. These may be symptoms of depression.

Tell your doctor immediately, or go to the Accident and Emergency at your nearest hospital if you notice any of the following:

- suicidal ideation or behaviour;
- epileptic attack (seizures);
- shaking or tremors;
- sudden muscle contractions (myoclonus);
- attack of excessive excitability (mania);
- agitation;
- confusion;
- hallucinations;
- changes to your heart rhythm;
- fainting;
- yellow colouring of eyes or skin; this may suggest disturbance in liver function;
- abdominal pain and nausea; this may suggest inflammation of the pancreas;
- generalised fluid retention with weight gain;
- skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty breathing;
- signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers; or
- a combination of symptoms such as fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive

reflexes, restlessness, mood changes, unconsciousness and increased salivation (serotonin syndrome).

The above list includes serious side effects that may require medical attention.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may get other effects while taking AUROZAPINE.

Ask your doctor or pharmacist if you don't understand anything in this list.

After taking it

Storage

Keep your tablets in the blister foil until it is time to take them.

If you take AUROZAPINE out of the blister foil, it will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store AUROZAPINE or any other medicine in the bathroom or near a sink.

Do not leave it on a windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What AUROZAPINE looks like

AUROZAPINE 15, 30 & 45 (15, 30 & 45 mg mirtazapine) are presented in pack size of 30 & 60 tablets in blister.

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.

AUROZAPINE 45

White, biconvex capsule shaped film-coated tablets with '10' debossed on one side and 'A' debossed on the other side.

*Some of these presentations and pack sizes may not be marketed.

Ingredients

Active ingredient:

Mirtazapine.

Other ingredients:

- lactose;
- hydroxypropylcellulose;
- maize starch;
- colloidal anhydrous silica;
- hydroxypropylcellulose;
- magnesium stearate;
- 15 mg tablet also contains Opadry Complete Film Coating System Yellow;

- 30 mg tablet also contains Opadry Complete Film Coating System Brown; and
- 45 mg tablet also contains Opadry Complete Film Coating System White.

Sponsor/Marketing Authorisation Holder

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