

TOLVON®

Mianserin hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tolvon.

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 Tolvon 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 Tolvon is used for

Tolvon is used in the treatment of depression.

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 imbalance 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 have prescribed Tolvon for another reason.

Ask your doctor if you have any questions about why it has been prescribed for you.

Tolvon is available only with a doctor's prescription.

Tolvon is not addictive.

Before you take it

When you must not take it

Do not take Tolvon:

- if you are allergic to medicines containing mianserin hydrochloride.
- if you are allergic to any of the ingredients listed at the end of this leaflet.

Some 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 troubled breathing.

Do not take Tolvon:

- if you suffer from mania, a mental condition characterised by episodes of overactivity, elation or irritability.
- if you have severe liver disease.

Do not take Tolvon if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days. If you stop taking Tolvon, do not take MAOI during the next 2 weeks either.

Examples of this type of medicine include phenelzine, moclobemide, tranylcypromine, selegiline and linezolid. Ask your doctor or pharmacist if you are unsure if you are or have been taking one of these medicines.

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

Do not take Tolvon if the expiry date printed on the pack has passed.

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

Before you start to take it

Do not give Tolvon to a child or adolescent.

There is limited experience with its use in children or adolescents under the age of 18 years.

Tell your doctor if:

1. **you have allergies to any other medicines, foods, dyes or preservatives.**
2. **you are pregnant or plan to become pregnant.**
Your doctor will discuss the risks and benefits of taking Tolvon during pregnancy.
3. **you are breastfeeding or wish to breastfeed.**
It is not known whether Tolvon passes into breast milk.

4. **you have, or have had, any medical conditions, especially the following:**
- epilepsy (fits or convulsions)
 - diabetes
 - liver disease such as jaundice
 - kidney disease
 - problems in urinating due to an enlarged prostate
 - heart disease, including certain kinds of heart conditions that change your heart rhythm, a recent heart attack, heart failure, or taking certain medicines known to change heart rhythm
 - blood pressure problems
 - glaucoma (increased pressure in the eye)
 - mental illness such as schizophrenia and manic depression (alternating periods of elation/overactivity and depressed mood)

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

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

- other medicines for depression
- Monoamine Oxidase Inhibitors (MAOIs)
- medicines used to treat epilepsy such as barbiturates, phenytoin and carbamazepine
- medicines used to treat high blood pressure
- oral antidiabetic medicines or insulin
- medicines used to prevent blood clots such as warfarin
- medicines that may affect the heart rhythm such as certain antibiotics and some anti-psychotics

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Tolvon.

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 and pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

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

Adults:

The usual starting dose is 30 mg per day. This may be given as a single night-time dose before going to bed or given in three divided doses. Your doctor may slowly increase this dose depending on how you respond to Tolvon. The effective dose for most people is usually between 30 mg and 90 mg per day.

Elderly:

The usual starting dose will not be more than 30 mg per day. Your doctor may slowly increase or decrease your dose depending on how you respond to Tolvon.

Your doctor may have prescribed a different dose.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How to take it

Swallow the tablet(s) whole with some water. Do not chew the tablets.

When to take it

Take Tolvon at about the same time each day, preferably between meals.

Your doctor will tell you when to take your tablets.

Taking it at the same time each day will have the best effect. It will also help you to remember when to take it.

How long to take it

Keep taking Tolvon 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 do not feel better right away. Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 or 6 weeks to feel the full benefit of Tolvon.

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

If you forget to take it

IF YOU TAKE ONE DOSE A DAY AT BEDTIME:

If you forget to take Tolvon before you go to bed and you wake up late in the night or early in the morning, do not take this medicine as it may cause drowsiness or sleepiness during the day.

IF YOU TAKE MORE THAN ONE DOSE A DAY:

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

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

If you take too much (overdose)

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

You may need urgent medical attention.

If you take too many tablets, you may feel drowsy, dizzy and light headed. There may also be a change in heart rhythm (fast, irregular heartbeat) and/or fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes. You may also have fits and problems breathing.

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 sign of frequent infections.

In rare cases, Tolvon can cause a shortage of white blood cells, resulting in the lowering of the body resistance to infection. These symptoms may 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 have 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 Tolvon, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment. These signs include:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self harm
- an 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 or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

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

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 your appointments with your doctor so that your progress can be checked. You may need to have blood tests from time to time.

Before starting any new medicine, tell your doctor or pharmacist that you are taking Tolvon.

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

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Tolvon.

Things you must not do

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

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

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

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

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

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

Do not stop taking Tolvon, even if you feel better unless advised by your doctor.

Do not use Tolvon to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

Do not drink alcohol while taking Tolvon.

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

Side Effects

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

Tolvon helps most people with depression, but it may have unwanted side effects in some 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 any questions you may have.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

- tiredness, drowsiness or lack of energy
- dizziness on standing up, especially when getting up from a sitting or lying position
- dizziness, faintness, weakness
- tremor
- headache
- dry mouth
- weight gain
- constipation
- restless legs
- ringing or persistent noise in the ears
- impotence
- breast enlargement in men
- nasal congestion
- hepatitis (inflammation of the liver)

Tell your doctor as soon as possible if you notice any of the following:

- skin rash
- itching
- painful, swollen joints
- aching muscles, muscle tenderness or weakness, not caused by exercise
- tingling or numbness of the hands and feet
- swelling of hands, feet and ankles due to build up of fluid

- vision problems
- confusion, agitation, irritability, hostility (aggressiveness), unusual changes in behaviour
- sudden switch of mood to one of excitement, overactivity, talkativeness and uninhibited behaviour

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

- you have thoughts of harming or killing yourself
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- bruising or bleeding more easily than normal, nosebleeds
- tiredness, headaches, being short of breath when exercising
- fits or convulsions
- yellowing of the eyes or skin (jaundice)
- slow heart beat
- changes to your heart rhythm (fast, irregular heartbeat) and/or fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes
- chest pain
- shortness of breath, swelling of the feet or legs due to fluid build up
- stiffness in the body, involuntary movements, a sudden increase in body temperature, extremely high blood pressure and severe convulsions (Neuroleptic Malignant Syndrome)

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.

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

After taking it

Storage

Store Tolvon in a cool, dry place where the temperature stays below 30°C. Protect from light.

Keep your tablets in their original container (blister) until it is time to take them.

Do not store Tolvon, or any other medicine, in the bathroom or near a sink. Do not leave Tolvon in the car or on window sills.

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

If your doctor tells you to stop taking Tolvon, or your tablets have passed their expiry date, ask your pharmacist what to do with any left over tablets.

Medicines should not be disposed of via wastewater or household waste. These measures will help protect the environment.

Product Description

What it looks like

- Tolvon 10 mg - white, film coated, round, biconvex, 6 mm in diameter, coded "CT" over "4" on one side and "Organon" and a star on the reverse.
- Tolvon 20 mg - white, film coated, round, biconvex, 7 mm diameter, coded "CT" over "6" on one side and "Organon" and a star on the reverse.

Tolvon is available in blister packs of 50 tablets.

Ingredients

The active ingredient in Tolvon is mianserin hydrochloride. Each tablet contains 10 mg or 20 mg of mianserin hydrochloride.

The tablets also contain the following inactive ingredients:

- Potato starch
- Silica colloidal anhydrous
- Magnesium stearate
- Methyl cellulose
- Calcium hydrogen phosphate
- Hypromellose
- Macrogol 8000
- Titanium dioxide (171)

Tolvon tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Tolvon is supplied in Australia by:
**Merck Sharp & Dohme (Australia)
Pty Limited**
Level 1 Building A
26 Talavera Road
Macquarie Park NSW 2113
Australia

Australian Registration Numbers:

Tolvon 10 mg - AUST R 65541
Tolvon 20 mg - AUST R 65543

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