

Molipaxin 50mg and 100mg Capsules

Trazodone hydrochloride



Is this leaflet hard to see or read?
Phone 01 4035600 for help

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. What Molipaxin Capsules are and what they are used for
2. What you need to know before you take Molipaxin Capsules
3. How to take Molipaxin Capsules
4. Possible side effects
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1. What Molipaxin Capsules are and what they are used for



The name of your medicine is Molipaxin 50mg or 100mg Capsules (called Molipaxin Capsules in this leaflet). Molipaxin Capsules contain a medicine called trazodone hydrochloride. This belongs to a group of medicines called antidepressants.

Molipaxin Capsules can be used to treat anxiety and depression.

2. What you need to know before you take Molipaxin Capsules

Do not take this medicine and tell your doctor if:

- × You are allergic (hypersensitive) to trazodone hydrochloride or any of the other ingredients of Molipaxin Capsules (listed in Section 6 Further information).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

Do not take this medicine if this applies to you. If you are not sure, talk to your doctor or pharmacist before taking Molipaxin Capsules.

Warnings and precautions

Take special care with Molipaxin Capsules. Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

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.

There have been reports of severe liver disorders with use of Molipaxin. If you experience any of the following symptoms you must contact your doctor immediately:

- weakness (asthenia)
- loss of appetite (anorexia)
- nausea, vomiting
- stomach pain
- yellowing of the skin and/or eyes (jaundice)

Elderly

Elderly patients when taking Molipaxin may experience light headedness and dizziness upon standing or stretching. They may also feel more drowsy or sleepy than usual.

Increased caution is necessary especially if the patient suffers from other ailments and is taking medications to treat these, along with taking Molipaxin.

Check with your doctor or pharmacist before taking this medicine if you:

- ▲ Have or have ever had fits or seizures
- ▲ Have severe liver, kidney or heart problems
- ▲ Are pregnant, trying to become pregnant or are breast-feeding

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Molipaxin Capsules.



Other medicines and Molipaxin

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Molipaxin Capsules can affect the way some other medicines work. Also some medicines can affect the way Molipaxin Capsules work.

Tell your doctor if you are taking any of the following medicines:

- MAOI (MonoAmine Oxidase Inhibitors) medicine
- such as tranylcypromine, phenelzine and isocarboxazid (for depression) or selegiline (for Parkinson's disease), **or have taken them in the last 2 weeks**
- Other antidepressants
- Sedatives (such as tranquilizers or sleeping pills)
- Medicines used to treat epilepsy such as carbamazepine and phenytoin
- Medicines used to treat high blood pressure, for example, clonidine
- Digoxin (used to treat heart problems)
- Medicines used to treat fungal infections such as ketoconazole and itraconazole
- Some medicines used to treat HIV such as ritonavir and indinavir
- Erythromycin, an antibiotic used to treat infections

Anaesthetics

If you are going to have an anaesthetic (for an operation), tell your doctor or dentist that you are taking Molipaxin Capsules.

Taking Molipaxin Capsules with food and drink

You should avoid drinking alcohol while taking Molipaxin Capsules.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.



Driving and using machines

Molipaxin Capsules may make you feel sleepy or dizzy. If this happens do not drive or use any tools or machines.

Important information about some of the ingredients of Molipaxin Capsules

Molipaxin Capsules contain lactose. If you have been told that you cannot digest or tolerate some sugars, talk to your doctor before taking trazodone.

3. How to take Molipaxin Capsules are given

Always take Molipaxin Capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth
- Swallow the capsules whole with a drink of water
- Take with or after food. This can help lower the chances of side effects
- If you have been told to take Molipaxin Capsules only once each day then you should take it before going to bed
- If you feel the effect of your medicine is too weak or
- too strong, do not change the dose yourself, but ask your doctor

How much to take

Adults:

Depression

- Adults usually start by taking 150mg each day.
- Your doctor may increase the dose to 300mg each day depending on your condition.
- For adults in hospital the dose may be as high as 600mg each day.

Anxiety

- Adults usually start by taking 75mg each day.
- Your doctor may increase the dose to 300mg each day.

Elderly:

Older people or those who are frail will usually be given a starting dose of 100mg each day.

Children:

Children should not take Molipaxin Capsules.

If you take more Molipaxin Capsules than you should

If you take more Molipaxin Capsules than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: feeling sick or being sick, feeling sleepy, dizzy or faint, fits (seizures), confusion, breathing or heart problems.

If you forget to take Molipaxin Capsules

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Molipaxin Capsules

Keep taking Molipaxin Capsules until your doctor tells you to stop. Do not stop taking Molipaxin Capsules just because you feel better. When your doctor tells you to stop taking these capsules he/she will help you stop taking them gradually.

4. Possible side effects

Like all medicines, Molipaxin Capsules can cause side effects, although not everybody gets them.

Stop taking Molipaxin Capsules and see a doctor or go to a hospital straight away if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty swallowing or breathing, itching of the skin and nettle rash. This may mean you are having an allergic reaction to Molipaxin Capsules.
- Painful erection of the penis, unrelated to sexual activity, that will not go away (priapism)
- Loss of appetite, feeling sick or being sick, confusion, abdominal pain, fever, yellowing of the eyes or skin (jaundice). These could be symptoms of a serious liver problem such as hepatitis
- Getting infections more easily than usual. This could be because of a blood disorder (agranulocytosis)
- Bruising more easily than usual. This could be because of a blood disorder (thrombocytopenia).

Talk to your doctor straight away if you notice any of the following side-effects:

- Feeling tired, faint, dizzy, having pale skin. These could be signs of anaemia
- Convulsions/fits
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)
- Feeling confused, restless, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles or a fast heartbeat, you may have something called Serotonin syndrome
- Feeling very unwell possibly with shortness of breath (dyspnoea), difficulty in walking or walking with a shuffling gait, shaking, uncontrolled muscle twitching, and a high temperature (above 38°C). This could be a rare condition known as Neuroleptic Malignant Syndrome

Below is a list of other side effects that have been reported:

- Feeling drowsy or sleepy (somnolence)
- Feeling less alert than usual
- Feeling sick (nausea) or being sick (vomiting)
- Constipation
- Diarrhoea
- Dry mouth
- Dizziness, headache, confusion, weakness, tremor (shaking)
- Blurred vision
- Weight loss
- Rapid or slow heartbeat
- Feeling dizzy or light-headed on standing or sitting up quickly (postural hypotension)
- Feeling restless and having difficulty sleeping
- Water retention which may cause swollen arms or legs
- Skin rash

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Molipaxin Capsules

Keep this medicine out of the sight and reach of children.

Do not use Molipaxin Capsules after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Molipaxin Capsules contain

- Each Molipaxin 50mg Capsule contains 50mg of the active substance, trazodone hydrochloride.
- Each Molipaxin 100mg Capsule contains 100mg of the active substance, trazodone hydrochloride.
- Other ingredients include lactose monohydrate, magnesium stearate, gelatin, titanium dioxide E171, erythrosine E127, indigo carmine E132, yellow iron oxide E172 and ink black containing shellac, iron oxide black (E172), propylene glycol, ammonium hydroxide OR shellac, iron oxide black (E172) propylene glycol, strong ammonia solution, potassium hydroxide. The 100mg Capsules also contain Red Iron Oxide E172.

What Molipaxin Capsules look like and contents of the pack

The 50mg capsules are opaque violet and green in colour and have the code 'R365B' imprinted on one side, the Roussel logo on the other. They are available in blister packs of 84 hard capsules.

The 100mg capsules are opaque, violet and fawn in colour and have the code 'R365C' imprinted on one side, the Roussel logo on the other. They are available in blister packs of 56 hard capsules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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