

PACKAGE LEAFLET: INFORMATION FOR THE USER

Molipaxin 50mg and 100mg Capsules

Trazodone hydrochloride

Is this leaflet hard to see or read?

Phone +353 1 428 7777 for help

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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.

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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 Contents of the pack and other information).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You consume alcohol or are taking sleeping tablets.
- You have recently had a heart attack.

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 disorder's 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)

Children

Molipaxin Capsules should not be used in children and adolescents under 18 years of age.

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

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:

- Monamine oxidase inhibitors (MAOI's) 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
- Phenothiazines - antipsychotic medicines used in the treatment of schizophrenia and other mental disorders
- Levodopa - used to treat Parkinson's disease
- Buprenorphine - used to treat pain. This medicine may interact with Molipaxin Capsules and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- 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
- Warfarin - used to stop your blood from clotting
- 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
- St. John's Wort - a herbal remedy

Anaesthetics

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

Molipaxin Capsules with alcohol

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.

Molipaxin Capsules should only be taken during pregnancy if recommended by your doctor.

Taking Molipaxin Capsules during pregnancy may lead to your baby experiencing withdrawal symptoms when they are born. In this case, monitoring of your newborn should be performed by your doctor. 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.

Molipaxin Capsules contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Molipaxin Capsules

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

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 and adolescents

Molipaxin Capsules should not be used in children or adolescents under 18 years of age.

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 strong, do not change the dose yourself, but ask your doctor

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 to take 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 to 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 the following side-effects:

- You have thoughts of harming or killing yourself
- Feeling tired, faint, dizzy, having pale skin. These could be signs of anaemia
- Rapid, slow or irregular heartbeat
- Convulsions/fits
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (parasthesia)
- 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 weak
- Feeling sick (nausea) or being sick (vomiting)
- Constipation
- Diarrhoea
- Dry mouth, altered taste, increased amounts of saliva
- Dizziness, headache, confusion, weakness, tremor (shaking)
- Blurred vision
- Weight loss
- Rapid or slow heartbeat
- Chest pain
- High blood pressure
- Feeling dizzy or light-headed on standing or sitting up quickly (postural hypotension), fainting
- Feeling agitated, restless, anxious or more nervous than normal,
- Difficulty sleeping, nightmares
- Decreased sex drive
- Overactive behaviour or thoughts (mania), believing things that are not true (delusions), memory disturbances
- Water retention which may cause swollen arms or legs
- Skin rash
- Pain in limbs, muscles or joints, flu like symptoms
- High temperature
- Frequent infections with high temperature, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called leucopenia.
- Difficulty with speaking
- Higher than normal number of white blood cells (shown in a blood test)
- Increased level of liver enzymes (shown in a blood test)
- Severe liver disorders such as hepatitis
- Liver failure with potentially fatal outcome
- Feeling tired, weak, confused, aching muscles. There may also be headache, loss of appetite, nausea or vomiting. This may be due to low sodium levels in your blood (shown in a blood test)

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 HPRA Pharmacovigilance

Website: www.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 contains

- 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, propylene glycol, black iron oxide E172, ammonium hydroxide or potassium hydroxide and ammonia solution.
The 100mg capsules also contain Red Iron Oxide E172.

What Molipaxin Capsules looks 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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