

PACKAGE LEAFLET: INFORMATION FOR THE USER

Molipaxin 50mg and 100mg Capsules

Trazodone hydrochloride

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist (see section 4).

In this leaflet:

1. What Molipaxin Capsules are and what they are used for
2. Before you take Molipaxin Capsules
3. How to take Molipaxin Capsules
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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. Before you take Molipaxin Capsules

Do not take this medicine and tell your doctor if you:

- are allergic to trazodone hydrochloride or any of the other ingredients of Molipaxin Capsules (listed in section 6). Signs of an allergic reaction can include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- have recently had a heart attack.
- are a heavy drinker or are taking sleeping tablets.
- are under 18 years of age.

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

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.
- 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.

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

If you are elderly, you may be more prone to side effects, increased caution is necessary especially when taking other medicines at the same time as Molipaxin or if you have some other diseases.

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

- have or have ever had fits or seizures (epilepsy)
- have severe liver, kidney or heart problems
- are pregnant, trying to become pregnant or are breast-feeding
- have an overactive thyroid gland (hyperthyroidism)
- have problems passing water or need to pass water (urine) frequently
- have narrow angle glaucoma (an eye disorder)
- have schizophrenia or other type of mental disorder
- are elderly, as you may be more prone to side effects
- are taking buprenorphine (a strong pain killer). The use of buprenorphine with Molipaxin Capsules can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Molipaxin Capsules").

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

Other medicines and Molipaxin Capsules

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) medicines 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 (such as amitriptyline or fluoxetine)
- **Buprenorphine/opioids.** These medicines 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)
- 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
- Levodopa (used to treat Parkinson's disease)
- St. John's Wort (a herbal remedy)
- Warfarin (used to stop your blood from clotting)

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.

Molipaxin Capsules should only be taken during pregnancy if your doctor tells you that treatment with Molipaxin Capsules is essential for you and tells you to take this medicine.

Taking Molipaxin Capsules in the late stages of pregnancy may lead to your baby experiencing withdrawal symptoms when they are born.

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.

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

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 and adolescents under 18 years 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 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)
- Yellowing of the eyes or skin. This could be a liver problem (such as jaundice)
- 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)
- You have severe abdominal pain and bloating, are being sick (vomiting) and have constipation. These may be signs that your intestine is not working properly (paralytic ileus)

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
- Convulsions/fits
- Unusual skin sensations such as numbness, tingling, prickling, burning or creeping on the skin (paresthesia)
- 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.
- Rapid, slow or irregular heartbeat.

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

- Feeling drowsy or sleepy, tiredness
- Feeling less alert than usual
- Feeling sick (nausea) or being sick (vomiting), indigestion
- Constipation, diarrhoea
- Dry mouth, altered taste, increased amounts of saliva, blocked nose
- Sweating more than usual
- Dizziness, headache, confusion, weakness, tremor (shaking)
- Blurred vision
- Loss of appetite and weight loss
- Feeling dizzy or light-headed on standing or sitting up quickly (postural hypotension), fainting (syncope)
- Feeling restless and having difficulty sleeping
- Water retention which may cause swollen arms or legs
- Skin rash, itching
- Chest pain
- Pain in limbs, back pain, pain in your muscles, pain in your joints
- Jerking movements that you can not control, mainly in the arms and legs, uncontrolled muscle movements or twitches
- Frequent infections with high temperature, severe chills, sore throat or mouth ulcers. These could be signs of a blood problem called leucopenia.
- Feeling anxious or more nervous than usual, feeling agitated
- Overactive behaviour or thoughts (mania), believing things that are not true (delusions), memory disturbance
- Nightmares
- Decreased sex drive
- Feeling dizzy, possibly with a "spinning" feeling (vertigo)

- High blood pressure
- High temperature
- Flu type symptoms
- Difficulty with speaking
- Higher than normal number of white blood cells (seen by a blood test)
- High levels of liver enzymes in your blood (shown by a blood test)
- Severe liver disorders such as hepatitis
- Liver failure with potentially fatal outcome
- Feeling tired, weak and confused, having muscle that ache, are stiff or do not work well. There may also be headache, loss of appetite, nausea or vomiting, convulsion. This may be due to low sodium levels in your blood.

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 the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 in a safe place where children cannot see or reach it.

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.

Store below 30°C in a dry place.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. 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, magnesium stearate, gelatin, titanium dioxide (E171), erythrosine (E127), indigo carmine (E132), yellow iron oxide (E172) and ink (black iron oxide E172, shellac, propylene glycol and ammonium hydroxide (pH adjustment) or black iron oxide E172, shellac, propylene glycol, strong ammonia solution (pH adjustment) and potassium hydroxide (pH adjustment)). The 100mg capsules also contain red iron oxide (E172).

What Molipaxin Capsules looks like and contents of the pack

Molipaxin 50mg capsules are violet and green, printed with the Roussel logo on one half and R365B on the other.

Molipaxin 100mg capsules are violet and fawn coloured, printed with the Roussel logo on one half and R365C on the other.

Molipaxin 50mg Capsules are supplied in blister packs of 84 and 100 capsules.

Molipaxin 100mg Capsules are supplied in blister packs of 56 and 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Zentiva Pharma UK Limited, 12 New Fetter Lane, London EC4A 1JP, United Kingdom

Manufacturer

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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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GENERAL INFO:

PM CODE:	ZV/678 76
PRODUCT NAME:	MOLIPAXIN CAP GB
SAP ID / GMID:	11008244, 11008246
AW VERSION:	V3
CREATION DATE:	21.02.2022
AW BY:	LN
SUPPLIER:	N/A

TECHNICAL INFO:

FORMAT (size):	160 x 400 mm
LAETUS (pharma code):	(5698) 011001000011; L - 0, C - 0, R - 1
FONT + MIN. SIZE:	Helvetica Neue LT W1G 9 pt
MATERIAL TYPE (TS):	PRG - see TS in eDMS

COLOURS: [1]

- Black

TECH. COLOURS: [1]

- DieCut