

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Trazodil 50; 100

Film-coated Tablets

Composition:

Each **Trazodil 50** film-coated tablet contains:

Trazodone hydrochloride 50 mg

Each **Trazodil 100** film-coated tablet contains:

Trazodone hydrochloride 100 mg

For the list of the inactive and allergenic ingredients in the preparation, see in section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Antidepressants increase the risk for suicidal behavior and thoughts in children, adolescents and young adults.

When starting treatment with the medicine, patients of all ages and their relatives must monitor behavioral changes, such as: worsening of depression, suicidal thoughts, aggressiveness and the like. If such changes occur, refer to a doctor immediately.

1. WHAT IS THE MEDICINE INTENDED FOR?

To treat states of depression and anxiety.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to trazodone hydrochloride or to any of the additional ingredients contained in the medicine (listed in section 6 "Further information"). Signs of an allergic reaction can include: rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- You recently had a heart attack.
- You consume large quantities of alcohol or take hypnotics.
- You are under 18 years of age.

Do not take this medicine if any of these points apply to you. If you are uncertain, consult the doctor or pharmacist before taking **Trazodil**.

Special warnings regarding use of the medicine

Exercise extra caution with Trazodil

Suicidal thoughts and worsening of depression and your anxiety disturbances

If you are suffering from depression and/or anxiety disturbances, you may sometimes have suicidal thoughts or thoughts of harming yourself. These effects may be increased at the beginning of treatment with antidepressants, since these medicines take time to start working, usually about two weeks but sometimes even more.

You may be more likely to think this way if:

- you have had suicidal thoughts or thoughts of harming yourself in the past.
- you are a young adult. Data from clinical trials have demonstrated an increase in the risk of suicidal behavior in adults under the age of 25 years with psychiatric conditions, who were treated with antidepressants.

If you have thoughts of harming yourself or suicidal thoughts at any time, contact your doctor or head straight for the hospital.

You may find it helpful to share with a relative or close friend that you are depressed or suffer from an anxiety disturbance; ask them to read this leaflet. You can ask them to tell you if they think that your depression or anxiety is worsening, or if they are concerned about changes in your behavior.

If you are elderly, you may have a tendency to develop side effects. Exercising extra caution is critical, especially if you are taking other medicines while taking **Trazodil** or if you are suffering from other ailments.

Before treatment with Trazodil, tell the doctor if:

- you have, or had at any time in the past, convulsions or seizures (epilepsy).
- you have serious liver, kidney or heart problems.
- you are pregnant, are trying to become pregnant or are breastfeeding.
- you are suffering from a hyperactive thyroid gland (hyperthyroidism).
- you are suffering from problems when passing urine or you urinate frequently.
- you are suffering from narrow-angle glaucoma (an eye disturbance).
- you are suffering from schizophrenia or from another mental illness.
- you are elderly – you may be more sensitive to side effects.
- you are taking buprenorphine (a strong painkiller). Use of buprenorphine together with **Trazodil** may lead to serotonin syndrome, a condition which may be life-threatening (see in section 2 “Drug interactions”).

If you are unsure if any of these points apply to you, speak to your doctor or pharmacist before taking **Trazodil**.

Children and adolescents

Trazodil is not intended for use in children and adolescents under 18 years of age.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. This is because **Trazodil** may affect the way other medicines work. Likewise, other medicines may affect the way **Trazodil** works.

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

- MAOIs (monoamine oxidase inhibitors) – medicines such as tranylcypromine, phenelzine and isocarboxazid (to treat depression) or selegiline (to treat Parkinson’s), or you have taken them in the last two weeks.

- Other antidepressants (such as amitriptyline or fluoxetine).
- Buprenorphine/opioids – these medicines may interact with **Trazodil** and you may experience symptoms such as involuntary, rhythmic muscle contractions, including the muscles that control eye movement, agitation, hallucinations, coma, excessive sweating, tremor, increased reflexes, increased muscle tension, body temperature above 38°C. Refer to your doctor if you experience such symptoms.
- Sedatives or hypnotics.
- Medicines to treat epilepsy, such as carbamazepine and phenytoin.
- Medicines to treat high blood pressure, such as clonidine.
- Digoxin (used to treat heart problems).
- Medicines to treat fungal infections, such as ketoconazole and itraconazole.
- Some medicines used to treat AIDS, such as ritonavir and indinavir.
- Erythromycin, an antibiotic used to treat infections.
- Levodopa (used to treat Parkinson's disease).
- Hypericum – St. John's wort (a herbal medicine).
- Warfarin (anticoagulant).
- Anesthetics – if you are due to receive anesthetics (for surgery), tell your doctor or dentist that you are taking **Trazodil**.

Use of the medicine and food

Swallow the medicine with water. The medicine can be taken with or after a meal, preferably in the evening hours, before bedtime.

Use of the medicine and alcohol consumption

Avoid drinking alcohol during the course of treatment with **Trazodil**.

Pregnancy, breastfeeding and fertility

If you are pregnant, might be pregnant or think you are pregnant, consult your doctor before taking the medicine.

Only take **Trazodil** during pregnancy if the doctor tells you that treatment with **Trazodil** is essential for you and tells you to take this medicine.

Taking **Trazodil** in the late stages of pregnancy may lead to withdrawal symptoms in the newborn.

If you are breastfeeding or plan to breastfeed, consult your doctor or pharmacist before taking any medicine.

Driving and using machinery

Use of this medicine may cause you to feel sleepy or dizzy. If this happens, do not drive or use tools or machinery.

Important information about some of the ingredients of the medicine

Trazodil tablets contain lactose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicinal product (also see section 6 "Further information").

Trazodil contains less than 1 mmol sodium (23 mg) per tablet, i.e., it is considered essentially "sodium-free".

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Dosage:

According to the doctor's instructions only. Do not exceed the recommended dose. This medicine is not intended for children and adolescents under 18 years of age.

If you forgot to take this medicine at the scheduled time, take a dose as soon as you remember, but never take two doses together!

Do not exceed the recommended dose.

Instructions for use:

Swallow the medicine with a little water. The medicine can be taken with or after a meal, preferably in the evening hours, before bedtime.

If necessary, the tablet can be halved for immediate use. There is no information about crushing or chewing.

If you accidentally took a higher dosage, immediately report to a doctor or proceed to a hospital emergency room. Bring the package of the medicine with you, so that the doctor will know what you have taken.

The following symptoms may occur: nausea or vomiting, sleepiness, dizziness or fainting, convulsions (seizures), confusion, breathing or heart problems.

If you forgot to take the medicine at the scheduled time, take it as soon as you remember, however, if it is almost time for the next dose, skip the forgotten dose and take the next dose at the usual time. Never take a double dose to compensate for the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine

Continue taking **Trazodil** until the doctor tells you to stop. Do not stop taking **Trazodil** just because you feel better. When the doctor tells you to stop taking the medicine, he will tell you how to do it gradually.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Trazodil** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop using the medicine and refer immediately to a doctor or hospital if the following side effects occur:

- Swelling of the hands, legs, ankles, face, lips or throat (which may cause difficulty swallowing or breathing), itching of the skin and urticaria. These effects may be indicative of an allergic reaction to **Trazodil**.
- Prolonged and painful erection, unrelated to sexual activity (priapism).

- Yellowing of the eyes or skin. This could be indicative of a liver problem (such as jaundice).
- Getting infections more easily than usual. This could be because of blood disorders (agranulocytosis).
- Bruising more easily than usual. This could be because of blood disorders (thrombocytopenia).
- Severe abdominal pains, bloating, vomiting and constipation. These may be a sign that your intestine is not working properly (paralytic ileus).

Tell the doctor immediately if you notice the following side effects:

- You have suicidal thoughts or thoughts of harming yourself.
- You feel tired, faint, dizzy, are pale (these could be signs of anemia).
- Convulsions/seizures.
- Unusual skin sensations, such as numbness, tingling, pricking, burning or creeping (paresthesia).
- Confusion, restlessness, sweating, tremor, hallucinations (seeing or hearing strange things), sudden jerks of the muscles or a fast heart rate (you may have serotonin syndrome).
- Feeling very unwell, sometimes with shortness of breath (dyspnea), difficulty in walking or walking with a shuffling gait, tremor, uncontrolled muscle twitching and a high fever (above 38°C). These can be signs of neuroleptic malignant syndrome.
- Rapid, slow or irregular heartbeat.

Additional side effects that have been reported:

- Feeling drowsy or sleepy, tiredness.
- Feeling less alert than usual.
- Nausea or vomiting, indigestion.
- Constipation, diarrhea.
- Dry mouth, altered taste, increased salivation, nasal congestion.
- Increased sweating.
- Dizziness, headache, confusion, weakness, tremor.
- Blurred vision.
- Loss of appetite and weight loss.
- Feeling dizzy on standing or sitting up quickly (postural hypotension), fainting (syncope).
- Feeling restless and having difficulty falling asleep.
- Water retention, which may cause swollen hands or legs.
- Skin rash, itching.
- Chest pains.
- Pain in the limbs, back pains, muscle pains, joint pains.
- Uncontrollable jerking movements, mainly in the hands and legs, uncontrollable muscle movements or twitches.
- Frequent infections with high fever, severe chills, sore throat or mouth ulcers. These could be symptoms of a blood problem called leukopenia.
- Feeling anxious or more nervous than usual, feeling agitated.
- Hyperactive behavior or thoughts (mania), believing things that are not true (delusions), memory disturbances.
- Nightmares.

- Decreased sex drive.
- Feeling dizzy, possibly with a “spinning” feeling (vertigo).
- High blood pressure.
- High fever.
- Flu symptoms.
- Difficulty speaking.
- Abnormal increase in white blood cell counts (seen in blood tests).
- High levels of liver enzymes in the blood (seen in blood tests).
- Severe liver disturbances, such as hepatitis.
- Liver failure, with a potentially fatal outcome.
- Feeling tired, weak and confused, muscle aches, stiffness or abnormal muscle activity. There may also be headaches, loss of appetite, nausea or vomiting, convulsions. This may be due to low sodium levels in your blood.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>. Additionally, they can be reported to “Unipharm Ltd.”.

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25°C and in a place protected from light.

6. FURTHER INFORMATION

In addition to the active ingredient the medicine also contains:

Lactose monohydrate, Dicalcium phosphate dihydrate, Microcrystalline cellulose, Maize starch, Sodium starch glycolate, Povidone, Magnesium stearate, Coating blend white.

Each **Trazodil 50** tablet contains 84.5 mg lactose.

Each **Trazodil 100** tablet contains 169 mg lactose.

What the medicine looks like and the contents of the package:

The medicine is packaged in trays (blisters) inserted into a carton package.

Each **Trazodil 50** package contains 30, 50 or 100 tablets.

Each **Trazodil 100** package contains 30, 50, 100 or 1,000 tablets.

Not all package sizes may be marketed.

Trazodil 50 – are white to off-white, round, biconvex film-coated tablets with a break line on one side.

Trazodil 100 – are white to off-white, round, biconvex film-coated tablets with a break line on one side.

Registration holder and address: Unipharm Ltd., P.O. Box 16545, Tel Aviv, 6116401.

Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.
Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Trazodil 50 – 029 10 20140 01

Trazoil 100 – 039 36 20141 02

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