

PATIENT INFORMATION LEAFLET

Mirtazapine Orally Disintegrating Tablets USP (7.5/15/30 mg)

DEZINE 7.5/15/30

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.

What is in this leaflet:

1. What Dezine 7.5/15/30 is and what it is used for
2. What you need to know before you take Dezine 7.5/15/30
3. How to take Dezine 7.5/15/30
4. Possible side effects
5. How to store Dezine 7.5/15/30
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1. What Dezine 7.5/15/30 is and what it is used for

Dezine 7.5/15/30 contains an active substance mirtazapine. It belongs to one of a group of medicines called antidepressants. It is used to treat depressive illness in adults. Dezine 7.5/15/30 will take 1 to 2 weeks before it starts working. After 2 to 4 weeks, you may start feeling better. You must talk to your doctor if you do not feel better or if you feel worse after 2 to 4 weeks.

2. What you need to know before you take Dezine 7.5/15/30

Do not take Dezine 7.5/15/30:

- ❖ if you are allergic to mirtazapine. If so, you must talk to your doctor as soon as you can before taking Dezine 7.5/15/30.
- ❖ if you are taking or have recently taken (within the last two weeks) medicines called monoamine oxidase inhibitors (MAO-Is).

Warnings and precautions

Talk to your doctor or pharmacist before taking Dezine 7.5/15/30.

Children and adolescents

Dezine 7.5/15/30 should normally not be used for children and adolescents under 18 years because efficacy was not demonstrated. Also, you should know that patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Dezine 7.5/15/30 for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Dezine 7.5/15/30 for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking Dezine 7.5/15/30.

Thoughts of suicide and worsening of your depression

If you are depressed, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines take time to work, usually about two weeks but sometimes longer. If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straightaway.

Also take special care with Dezine 7.5/15/30

- ❖ if you have, or have ever had one of the following conditions. Tell your doctor about these conditions immediately before taking Dezine 7.5/15/30.
- ❖ seizures (epilepsy), liver disease including jaundice, kidney disease, heart disease, or low blood pressure, schizophrenia, manic depression, diabetes (you may need to adjust your dose of insulin or other antidiabetic medicines), eye disease such as increased pressure in the eye (glaucoma), difficulty in passing water urinating, certain kinds of heart conditions that may change your heart rhythm, a recent heart attack, heart failure, or take certain medicines that may affect the heart's rhythm.
- ❖ if you develop signs of infection such as inexplicable high fever, sore throat and mouth ulcers. Stop taking Dezine 7.5/15/30 and consult your doctor immediately for a blood test.
- ❖ if you are an elderly person. You could be more sensitive to the side-effects of antidepressants.

Other medicines and Dezine 7.5/15/30

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

Do not take Dezine 7.5/15/30 in combination with:

- ❖ monoamine oxidase inhibitors (MAO inhibitors). Examples of MAO inhibitors are moclobemide, tranylcypromine (both are antidepressants) and selegiline (used for Parkinson's disease).

Take care when taking Dezine 7.5/15/30 in combination with:

- ❖ antidepressants such as SSRIs, venlafaxine and L-tryptophan or triptans (used to treat migraine), tramadol (a pain-killer), linezolid (an antibiotic), lithium (used to treat some psychiatric conditions), methylene blue (used to treat high levels of methemoglobin in the blood) and St. John's Wort – Hypericum perforatum preparations (a herbal remedy for depression).
- ❖ the antidepressant nefazodone. It can increase the amount of Dezine 7.5/15/30 in your blood.
- ❖ medicines for anxiety or insomnia such as benzodiazepines; medicines for schizophrenia such as olanzapine; medicines for allergies such as cetirizine; medicines for severe pain such as morphine. In combination with these medicines, Dezine 7.5/15/30 can increase the drowsiness caused by these medicines.
- ❖ medicines for infections; medicines for bacterial infections (such as erythromycin, medicines for fungal infections (such as ketoconazole) and medicines for HIV/AIDS (such as HIV/protease inhibitors) and drugs for stomach ulcers (such as cimetidine). In combination with Dezine 7.5/15/30 these medicines can increase the amount of Dezine 7.5/15/30 in your blood.
- ❖ medicines for epilepsy such as carbamazepine and phenytoin; medicines for tuberculosis such as rifampicin. In combination with Dezine 7.5/15/30 these medicines can reduce the amount of Dezine 7.5/15/30 in your blood.
- ❖ medicines to prevent blood clotting such as warfarin. Dezine 7.5/15/30 can increase the effects of warfarin on the blood.
- ❖ medicines that may affect the heart's rhythm such as certain antibiotics and some antipsychotics.

Dezine 7.5/15/30 with food and alcohol

You may get drowsy if you drink alcohol while you are taking Dezine 7.5/15/30. You are advised not to drink any alcohol. You can take Dezine 7.5/15/30 with or without food.

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Limited experience with Dezine 7.5/15/30 administration to pregnant women does not indicate an increased risk. However, caution should be exercised when used during pregnancy. If you use Dezine 7.5/15/30 until, or shortly before birth, your baby should be supervised for possible adverse effects.

When taken during pregnancy, similar drugs (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby you should contact your doctor immediately.

Driving and using machines

Dezine 7.5/15/30 can affect your concentration or alertness. Make sure these abilities are not affected

before you drive or operate machinery. If your doctor has prescribed Dezine 7.5/15/30 for a patient under 18 years make sure the concentration and alertness is not affected before participation in traffic (e.g. on bicycle).

3. How to take Dezine 7.5/15/30

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

The recommended starting dose is one tablet every day. Your doctor may advise you to increase your dose after a few days to the amount that is best for you (between 15 and 45 mg per day). The dose is usually the same for all ages. However, if you are an elderly person or if you have renal or liver disease, your doctor may adapt the dose.

When to take Dezine 7.5/15/30

Take Dezine 7.5/15/30 at the same time each day. It is best to take Dezine 7.5/15/30 as a single dose before you go to bed. However your doctor may suggest to split your dose of Dezine 7.5/15/30 – once in the morning and once at night-time before you go to bed. The higher dose should be taken before you go to bed.

How to take Dezine 7.5/15/30

Take your tablets orally. Take out the tablets with dry hands and place it on the tongue. It will disintegrate and can be swallowed without water.

When can you expect to start feeling better

Usually Dezine 7.5/15/30 will start working after 1 to 2 weeks and after 2 to 4 weeks you may start to feel better. It is important that, during the first few weeks of the treatment, you talk with your doctor about the effects of Dezine 7.5/15/30:

- ❖ 2 to 4 weeks after you have started taking Dezine 7.5/15/30, talk to your doctor about how this medicine has affected you.

If you still don't feel better, your doctor may prescribe a higher dose. In that case, talk to your doctor again after another 2 to 4 weeks. Usually you will need to take Dezine 7.5/15/30 until your symptoms of depression have disappeared for 4 to 6 months.

If you take more Dezine 7.5/15/30 than you should

If you or someone else has taken too much Dezine 7.5/15/30, call a doctor straightaway. The most likely signs of an overdose of Dezine 7.5/15/30 (without other medicines or alcohol) are drowsiness, disorientation and increased heart rate. The symptoms of a possible overdose may include changes to your heart rhythm (fast, irregular heartbeat) and/or fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes.

If you forget to take Dezine 7.5/15/30

If you are supposed to take your dose once a day

- ❖ Do not take a double dose to make up for a forgotten dose. Take your next dose at the normal time.

If you are supposed to take your dose twice a day

- ❖ if you have forgotten to take your morning dose, simply take it together with your evening dose.
- ❖ if you have forgotten to take your evening dose, do not take it with the next morning dose; just skip it and continue with your normal morning and evening doses.
- ❖ if you have forgotten to take both doses, do not attempt to make up for the missed doses. Skip both doses and continue the next day with your normal morning and evening doses.

If you stop taking Dezine 7.5/15/30

Stop taking Dezine 7.5/15/30 only in consultation with your doctor.

If you stop too early, your depression might come back. Once you are feeling better, talk to your

doctor. Your doctor will decide when treatment can be stopped.

Do not suddenly stop taking Dezine 7.5/15/30, even when your depression has lifted. If you suddenly stop taking Dezine 7.5/15/30, you may feel sick, dizzy, agitated or anxious, and have headaches. These symptoms can be avoided by stopping gradually. Your doctor will tell you how to decrease the dose gradually.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following serious side effects, stop taking mirtazapine and tell your doctor immediately.

Uncommon (may affect up to 1 in 100 people):

- ❖ feeling elated or emotionally 'high' (mania).

Rare (may affect up to 1 in 1,000 people):

- ❖ yellow colouring of eyes or skin; this may suggest disturbance in liver function (jaundice).

Other possible side effects with mirtazapine are:

Very common (may affect more than 1 in 10 people):

- ❖ increase in appetite and weight gain, drowsiness or sleepiness, headache, dry mouth.

Common (may affect up to 1 in 10 people):

- ❖ lethargy, dizziness, shakiness or tremor, nausea, diarrhea, vomiting, constipation, rash or skin eruptions (exanthema), pain in your joints (arthralgia) or muscles (myalgia), back pain, feeling dizzy or faint when you stand up suddenly (orthostatic hypotension), swelling (typically in ankles or feet) caused by fluid retention (oedema), tiredness, vivid dreams, confusion, feeling anxious, sleeping problems.

Additional side effects in children and adolescents

In children under 18 years the following adverse events were observed commonly in clinical trials: significant weight gain, hives and increased blood triglycerides.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Dezine 7.5/15/30

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture. Store in a dry place at or below 30°C.

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 protect the environment.

6. Contents of the pack and other information

What Dezine 7.5/15/30 contains

The active ingredient is Mirtazapine.

Each uncoated orally disintegrating tablet contains:

Mirtazapine USP 7.5 mg

Colour: Sunset/Yellow Lake

Each uncoated orally disintegrating tablet contains:

Mirtazapine USP 15 mg

Colour: Iron Oxide/Yellow

Each uncoated orally disintegrating tablet contains:

Mirtazapine USP 30 mg

Colour: Brilliant Blue/Lake

What Dezine 7.5/15/30 looks like and contents of the pack

Dezine 7.5 is light orange coloured, round, biconvex, uncoated tablet with 'Q' logo scored on one side. It is available in a blister strip using HSL coated printed aluminium foil on one side and plain cold forming foil on the other side. The pack size is 10 x 10 tablets in a printed carton.

Dezine 15 is light yellow coloured, round, biconvex, uncoated tablet with 'Q' logo scored on one side. It is available in a blister strip using HSL coated printed aluminium foil on one side and plain cold forming foil on the other side. The pack size is 10 x 10 tablets in a printed carton.

Dezine 30 is light blue coloured, round, biconvex, uncoated tablet with breakline on one side. It is available in a blister strip using HSL coated printed aluminium foil on one side and plain cold forming foil on the other side. The pack size is 10 x 15 tablets in a printed carton.



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