

# Mirtazapine 15mg Orodispersible Tablets

## Mirtazapine 30mg Orodispersible Tablets

### Mirtazapine 45mg Orodispersible Tablets

#### Mirtazapine



#### 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. See section 4.

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#### 1 What Mirtazapine Orodispersible tablets are and what they are used for

Mirtazapine is one of a group of medicines called **antidepressants**. Mirtazapine is used to treat depressive illness.

#### 2 What you need to know before you take Mirtazapine Orodispersible tablets

##### Do not take Mirtazapine

- If you are allergic to mirtazapine or any of the other ingredients of this medicine (listed in section 6).
- If you are taking or have recently taken (within the last two weeks) medicines called monoamine oxidase inhibitors (MAO-Is).

**Do not take - or - Tell your doctor before taking mirtazapine:** If you have ever developed a **severe skin rash or skin peeling, blistering and/or mouth sores** after taking mirtazapine or other medicinal product(s).

##### Warnings and precautions

###### Children and adolescents

Mirtazapine should normally not be used for children and adolescents under 18 years. 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 Mirtazapine Orodispersible tablets for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Mirtazapine Orodispersible tablets 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 Mirtazapine Orodispersible tablets. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Mirtazapine in this age group have not yet been demonstrated.

###### 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 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, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

###### Take special care with mirtazapine:

Serious skin reactions including **Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS)** have been reported with the use of mirtazapine. Stop using and seek medical attention immediately if you notice any of the symptoms described in section 4 in relation to these serious skin reactions. If you have ever developed any severe skin reactions, treatment with mirtazapine should not be restarted.

Talk to your doctor or pharmacist before taking Mirtazapine Orodispersible tablets

- if you have, or have ever had one of the following conditions. Tell your doctor about these conditions before taking Mirtazapine Orodispersible tablets, if not done previously.
  - **seizures** (epilepsy). If you develop seizures or your seizures become more frequent, stop taking Mirtazapine Orodispersible tablets and contact your doctor immediately
  - **liver disease**, including jaundice. If jaundice occurs, stop taking Mirtazapine Orodispersible tablets and contact your doctor immediately
  - **kidney disease**
  - **heart disease, or low blood pressure**
  - **schizophrenia**. If psychotic symptoms, such as paranoid thoughts become more frequent or severe, contact your doctor straight away
  - **manic depression** (alternating periods of feeling elated/overactivity and depressed mood). If you start feeling elated or over-excited, stop taking Mirtazapine Orodispersible tablets and contact your doctor immediately
  - **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), which might be caused by an enlarged prostate.
- if you develop signs of infection such as inexplicable high fever, sore throat and mouth ulcers.
  - Stop taking Mirtazapine Orodispersible tablets and consult your doctor immediately for a blood test.

In rare cases these symptoms can be signs of disturbances in blood cell production in the bone marrow. While rare, these symptoms most commonly appear after 4-6 weeks of treatment.

- if you are an elderly person. You could be more sensitive to the side effects of antidepressants.

###### Other medicines and Mirtazapine Orodispersible tablets

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

**Do not take Mirtazapine Orodispersible tablets** in combination with:

- monoamine oxidase inhibitors** (MAO inhibitors). Also, do not take Mirtazapine Orodispersible tablets during the two weeks after you have stopped taking MAO inhibitors. If you stop taking Mirtazapine Orodispersible tablets, do not take MAO inhibitors during the next two weeks either.

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

**Take care when** taking Mirtazapine Orodispersible tablets 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 methaemoglobin in the blood) and **St. John's Wort – Hypericum perforatum preparations** (a herbal remedy for depression). In very rare cases, Mirtazapine Orodispersible tablets alone or the combination of Mirtazapine Orodispersible tablets with these medicines, can lead to a so-called serotonin syndrome. Some of the symptoms of this syndrome are: inexplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes, and unconsciousness. If you get a combination of these symptoms, talk to your doctor immediately.
- the antidepressant nefazodone**. It can increase the amount of mirtazapine in your blood. Inform your doctor if you are using this medicine. It might be needed to lower the dose of Mirtazapine Orodispersible tablets, or when use of nefazodone is stopped, to increase the dose of Mirtazapine Orodispersible tablets again.
- 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 Mirtazapine Orodispersible tablets 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 Mirtazapine Orodispersible tablets these medicines can increase the amount of Mirtazapine in your blood. Inform your doctor if you are using these medicines. It might be needed to lower the dose of Mirtazapine Orodispersible tablets, or when these medicines are stopped, to increase the dose of Mirtazapine Orodispersible tablets again.
- medicines for epilepsy** such as carbamazepine and phenytoin;
- medicines for tuberculosis** such as rifampicin. In combination with Mirtazapine Orodispersible tablets these medicines can reduce the amount of Mirtazapine in your blood. Inform your doctor if you are using these medicines. It might be needed to increase the dose of Mirtazapine Orodispersible tablets, or when these medicines are stopped to lower the dose of Mirtazapine Orodispersible tablets again.
- medicines to prevent blood clotting** such as warfarin. Mirtazapine can increase the effects of warfarin on the blood. Inform your doctor if you are using this medicine. In case of combination it is advised that a doctor monitors your blood carefully.
- medicines that may affect the heart's rhythm** such as certain antibiotics and some antipsychotics.

###### Mirtazapine Orodispersible tablets with food and alcohol

You may get drowsy if you drink alcohol while you are taking Mirtazapine Orodispersible tablets.

You are advised not to drink any alcohol.

You can take Mirtazapine Orodispersible tablets with or without food.

###### Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Limited experience with Mirtazapine administration to pregnant women does not indicate an increased risk. However, caution should be exercised when used during pregnancy.

If you are taking Mirtazapine Orodispersible tablets and you become pregnant or you plan to get pregnant, ask your doctor whether you may continue taking Mirtazapine Orodispersible tablets. If you use Mirtazapine until, or shortly before birth, your baby should be supervised for possible adverse effects.

Make sure your midwife and/or doctor know you are on Mirtazapine.

When taken during pregnancy, similar drugs (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the new born (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 midwife and/or doctor immediately.

Ask your doctor whether you can breast-feed, while taking Mirtazapine Orodispersible tablets.

###### Driving and using machines

Mirtazapine can affect your concentration or alertness. Make sure these abilities are not affected before you drive or operate machinery.

###### Mirtazapine Orodispersible tablets contain aspartame, a source of phenylalanine

This medicine contains 6mg, 12mg, 18mg aspartame in each 15mg, 30mg, 45mg orodispersible tablet respectively. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

#### 3 How to take Mirtazapine Orodispersible tablets

Always take this medicine exactly as your doctor or pharmacist tells you to. You should check with your doctor or pharmacist if you are not sure.

##### The recommended dose is

**The usual starting dose is 15 or 30mg every day.** Your doctor may advise you to increase your dose after a few days to the amount that may be best for you (between 15 and 45mg 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 Mirtazapine Orodispersible tablets

Take Mirtazapine Orodispersible tablets at the same time each day.

It is best to take Mirtazapine Orodispersible tablets as a single dose before you go to bed. However your doctor may suggest to split your dose of Mirtazapine Orodispersible tablets – 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.

##### Take the orodispersible tablets as follows;

Take your tablets orally.

##### 1. Tear off one tablet pocket

Each blister contains ten pockets, which are separated by perforations. Tear off one tablet pocket along the dotted lines (Figure 1).



## 2. Take out the orodispersible tablet

Take the tablet out of the blister pocket with dry hands and place it on the tongue (Figure 2). It will rapidly disintegrate and can be swallowed without water.



### When can you expect to start feeling better

Usually, Mirtazapine Orodispersible tablets 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 to your doctor about the effects of Mirtazapine Orodispersible tablets:

2 to 4 weeks after you have started taking Mirtazapine Orodispersible tablets, 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 Mirtazapine Orodispersible tablets until your symptoms of depression have disappeared for 4 to 6 months.

### If you take more Mirtazapine Orodispersible tablets than you should

If you or someone else have taken too many Mirtazapine Orodispersible tablets, call a doctor straight away. The most likely signs of an overdose of Mirtazapine Orodispersible tablets (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 Mirtazapine Orodispersible tablets

If you are supposed to take your dose **once a day**

- if you have forgotten to take your dose of Mirtazapine Orodispersible tablets, do not take a double dose to make up for a forgotten dose. Just skip it. 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 Mirtazapine Orodispersible tablets

Only stop taking Mirtazapine Orodispersible tablets 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 Mirtazapine Orodispersible tablets, even when your depression has lifted. If you suddenly stop taking Mirtazapine Orodispersible tablets 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.

### Stop taking Mirtazapine Orodispersible tablets and tell your doctor straight away if you experience the following side effects:

- **Common** (may affect up to 1 in 10 people):
  - memory problems, which in most cases resolved when treatment was stopped.
- **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)
- severe upper abdominal pain often with nausea and vomiting (pancreatitis).

**Not known** (frequency cannot be estimated from the available data):

- thoughts of harming or killing yourself – **contact your doctor or go to a hospital straight away.**
- a skin reaction known as 'erythema multiforme' (itchy reddish purple patches on the skin, especially on the palms of the hands or soles of the feet, 'hive-like' raised swollen areas on the skin, tender areas on the surfaces of the mouth, eyes and genitals, which may be accompanied by fever and tiredness).
- severe rash, blistering (bullous dermatitis).
- reddish patches on the trunk which are target-like macules or circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers (agranulocytosis). In rare cases mirtazapine can cause disturbances in the production of blood cells (bone marrow depression). Some people become less resistant to infection because mirtazapine can cause a temporary shortage of white blood cells (granulocytopenia). In rare cases mirtazapine can also cause a shortage of red and white blood cells, as well as blood platelets (aplastic anaemia), a shortage of blood platelets (thrombocytopenia) or an increase in the number of white blood cells (eosinophilia).
- epileptic attack (convulsions).
- a combination of symptoms such as inexplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, mood changes, unconsciousness and increased salivation. In very rare cases these can be signs of serotonin syndrome.
- muscle pain, stiffness and/or weakness and darkening or discolouration of the urine (rhabdomyolysis).

### Other possible side effects with Mirtazapine tablets 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
- diarrhoea
- 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.

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

- abnormal sensation in the skin e.g. burning, stinging, tickling or tingling (paraesthesia)
- restless legs
- fainting (syncope)
- sensations of numbness in the mouth (oral hypoaesthesia)
- low blood pressure
- nightmares
- feeling agitated
- hallucinations
- urge to move.

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

- muscle twitching or contractions (myoclonus)
- feeling aggressive.

**Not known** (frequency cannot be estimated from the available data):

- abnormal sensations in the mouth (oral paraesthesia)
- swelling in the mouth (mouth oedema)
- swelling throughout the body (generalised oedema)
- localised swelling
- low sodium in the blood (hyponatraemia)
- inappropriate secretion of a hormone, which regulates the amount of water in the blood (anti-diuretic hormone)
- increased salivation
- slurred speech (dysarthria)
- sleepwalking (somniaambulism)
- difficulty in passing urine
- increased creatine kinase blood levels
- increased prolactin hormone levels in the blood (hyperprolactinemia, including symptoms of enlarged breasts and/or milky nipple discharge).

### 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, 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](http://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 Mirtazapine Orodispersible tablets

Keep out of the sight and reach of children.

Do not store above 25°C.

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

Store in the original package in order to protect from light and moisture.

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 Mirtazapine Orodispersible tablets contain

- The active substance is mirtazapine. Mirtazapine 15mg orodispersible tablets contain 15mg mirtazapine per orodispersible tablet. Mirtazapine 30mg orodispersible tablets contain 30mg mirtazapine per orodispersible tablet. Mirtazapine 45mg orodispersible tablets contain 45mg mirtazapine per orodispersible tablet.

The other ingredients are mannitol, microcrystalline cellulose, magnesium carbonate heavy, hydroxypropyl cellulose low substituted, crospovidone (Polyplasdone XL-10), silica colloidal anhydrous, L-Methionine, purified water, microcrystalline cellulose and Guar Gum (Avicel CE-15), aspartame (E951), orange flavour Silesia 1209603133, magnesium stearate.

### What Mirtazapine Orodispersible tablets look like and contents of the pack

Mirtazapine Orodispersible tablets are orodispersible tablets. Mirtazapine 15mg orodispersible tablets are white or almost white, 8 mm round, biconvex, uncoated tablets and marked M5.

Mirtazapine 30mg orodispersible tablets are white or almost white, 10 mm round, biconvex, uncoated tablets and marked M6.

Mirtazapine 45mg orodispersible tablets are white or almost white, 12 mm round, biconvex, uncoated tablets and marked M4.

For Mirtazapine 15, 30 and 45mg orodispersible tablets the following pack sizes are available:

The tablets are supplied in blister and bottle packs of 5, 6, 7, 10, 14, 15, 20, 21, 28, 30, 50, 56, 60, 84, 90, 98 and 100 Tablets.

Not all pack sizes may be marketed.

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