Package leaflet: Information for the user

Mirtazapine 15mg, 30mg and 45mg Orodispersible Tablets
mirtazapine

Warning – Thoughts of self- harm and suicidal behaviour – see section 2

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. Do not pass it on to others. It may harm them, even if their symptoms 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.

What is in this leaflet

1. What Mirtazapine Orodispersible Tablets are and what they are used for
2. What you need to know before you take Mirtazapine Orodispersible Tablets
3. How to take Mirtazapine Orodispersible Tablets
4. Possible side effects
5. How to store Mirtazapine Orodispersible Tablets
6. Contents of the pack and other information

1. What Mirtazapine Orodispersible Tablets are and what they are used for
Mirtazapine belongs to a group of medicines called antidepressants and is used to treat depression. It may take 2 to 4 weeks before you start to feel or sleep better. It is important to take Mirtazapine every day and not to stop taking it unless your doctor tells you to. If you do, your symptoms may come back.

2. What you need to know before you take Mirtazapine Orodispersible Tablets
Do not take Mirtazapine Orodispersible Tablets:
- If you are **allergic** (hypersensitive) to Mirtazapine or any of the other ingredients of Mirtazapine Orodispersible Tablets (see section 6).
- If you are taking or have recently taken (within the last two weeks) medicines called monoamine oxidase inhibitors (MAOIs).

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
Talk to your doctor or pharmacist or nurse before taking Mirtazapine Orodispersible Tablets if you have, or ever had:
- epilepsy (seizures or fits)
- kidney or liver disease (including jaundice)
- heart disease or a family history of heart disorders
- other heart conditions including heart attack, irregular heartbeat or heart failure, or are taking medicines that may affect the rhythm of your heart
- low blood pressure
- difficulty in passing water (urinating), which may be caused by an enlarged prostate
- eye disease, such as glaucoma (increased pressure in eyes)
- diabetes (you may need to adjust your dose of insulin or other antidiabetic medicines)

• 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 get inexplicable high fever, sore throat or mouth ulcers and recurrent minor infections such as coughs and colds.
• Stop taking Mirtazapine Orodispersible tablets and consult your doctor immediately for a blood test. In rare cases there may be changes in the white blood cells production in bone marrow. 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 antidepressant.

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.

Children and adolescents under 18 years of age

Mirtazapine Orodispersible Tablets should not normally 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 (mainly aggression, oppositional behaviour and anger) when they take this type of medicine. Despite this, your doctor may prescribe Mirtazapine Orodispersible Tablets for patients under 18 because they have decided 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 in this age group have not yet been demonstrated. In addition, significant weight gain has been observed in this age category more often when treated with Mirtazapine Orodispersible Tablets compared with adults.

Thoughts of suicide and worsening of your depression
This medicine may be associated with thoughts of self-harm and suicidal behaviour in some people.
Tell someone you trust, who can help you in an emergency, that you are taking this medicine and ask that they read this leaflet
Talk to your trusted person, prescriber or go to a hospital straight away, if after starting this medicine, you have new or worse:

- Feelings of anxiety or irritability
- Feelings of restlessness and agitation
- Extreme increases in activity and difficulty sleeping
- Thoughts of acting on dangerous impulses to harm yourself
- Thoughts about suicide or dying
- Changes in behaviour or mood you, or someone you trust, notices and is worried about

In some people, thoughts of self-harm and suicidal behaviour may be increased when first starting antidepressants. Antidepressants take time to work; and sometimes side effects occur before you or others notice improvements in your mood.
Never stop taking an antidepressant suddenly without first talking to a healthcare professional. Stopping an antidepressant medicine suddenly can cause other symptoms related to withdrawal to occur.

Information from clinical trials has shown the highest risk of thoughts of self harm and suicidal behaviour, is in adults aged less than 25 years who were treated with an antidepressant but the risk applies to people of all ages treated with these medicines.
Call NHS 111 who can offer you support, until you can be with someone who can help you in person.

Other medicines and Mirtazapine Orodispersible Tablets
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

• **Other antidepressants:**
You should not take Mirtazapine Orodispersible Tablets if you are taking other antidepressants known as Monoamine Oxidase Inhibitors (MAOIs), or in the two weeks after they have been stopped. The use of other antidepressants or medicines containing the product serotonin can lead to the development of serotonin syndrome and should be used with caution.
Examples of MAO inhibitors are moclobemide, tranylcypromine (both are antidepressants) and selegiline (used for Parkinson's disease).

• **Take care when taking any of the following medicines:**
- 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) 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.

- Nefazodone, an antidepressant- It can increase the amount of Mirtazapine Orodispersible tablets 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.

-Drugs for anxiety or insomnia: Mirtazapine Orodispersible tablets can increase the drowsiness caused by 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 tuberculosis such as rifampicin;
- Drugs for epilepsy e.g. phenytoin or carbamazepine.

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.

- Drugs to prevent blood clotting e.g. 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.

Mirtazapine Orodispersible tablets with food and alcohol
You may get drowsy if you drink alcohol while you are taking Mirtazapine Orodispersible Tablets. It is therefore advisable to avoid drinking any alcohol.
You can take Mirtazapine Orodispersible tablets with or without food.

Pregnancy and breast-feeding
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 Mirtazapine Orodispersible Tablets 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 Orodispersible Tablets until, or shortly before birth, your baby should be supervised for possible adverse effects. Make sure your midwife and/or doctor knows you are on Mirtazapine Orodispersible Tablets. 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 make you feel drowsy, affect your concentration or make you less alert. When you first start taking Mirtazapine, make sure your abilities are not affected before you drive or operate machinery.

Mirtazapine Orodispersible tablets contains Aspartame
Mirtazapine Orodispersible Tablets contain Aspartame 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 Mirtazapine Orodispersible Tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is
Adults and elderly patients:

The usual starting dose is 15mg or 30mg every day taken preferably in the evening. 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.

Duration of treatment

After 2 to 4 weeks, talk to your doctor about the effect the treatment has had. If you still don't feel well, your doctor may prescribe a higher dose. After another 2 to 4 weeks talk to your doctor again.

Route and method of administration

Take Mirtazapine at the same time each day. Your doctor will probably advise you to take Mirtazapine as a single dose before you go to bed. However, your doctor may suggest you split your dose – for example once in the morning, and once before you go to bed. The higher dose should be taken before you go to bed.

Take the orodispersible tablets as follows:

Take your tablet orally.

Fig A. Do not crush the orodispersible tablet

Keep your hands dry. Do not push the tablet out of the pocket (fig A). You will crush it.



Fig B. Tear off one tablet pocket

Each blister contains six tablets. The tablets are in pockets separated by perforations. Tear off one tablet pocket along the dotted line (Fig B).

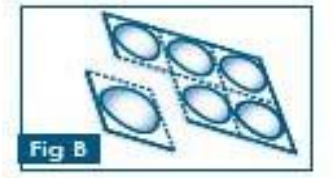


Fig C. Peel off the lid

Carefully peel off the lidding foil starting at the corner with the black arrow (Figs C and D)





Fig E. Take out the orodispersible tablet

Fig E. Take out the orodispersible tablet

Take the tablet out of the pocket with dry hands and place it on your tongue (Fig E). The tablet will disintegrate and can be swallowed with or 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 with 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
Call a doctor straight away or go immediately to the nearest casualty department, taking the remaining tablets with you. The most likely signs of an overdose of Mirtazapine Orodispersible tablets (without other medicines or alcohol) are drowsiness, disorientation and increased heart rate.

If you forget to take Mirtazapine Orodispersible tablets
If you are supposed to take your dose **once a day**: do not take a double dose to make up for forgotten individual doses. Just skip that dose and take your next one 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

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 even if your depression has lifted. If you stop suddenly, you may feel sick, anxious or agitated and have headaches. It is possible that some of your symptoms may come back. Once you are feeling better, talk to your doctor who will tell you how to reduce the dose gradually. This will usually be about 4 to 6 months after you start feeling better.

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.

Please remember that it can sometimes be hard to tell the difference between some of the milder side effects and the symptoms of your depression.

Serious side effects
Stop taking Mirtazapine Orodispersible tablets and tell your doctor straight away if you experience the following:
•thoughts of harming or killing yourself.
•Skin blistering or inflammation (Dermatitis bullous), widespread skin (blistering) rash – circular, irregular red patches on the skin of the hands and arms (Erythema multiforme) and

blistering or scaling decay of the skin.
•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).
• feeling elated or emotionally 'high' (mania)
• yellow colouring of eyes or skin; this may suggest disturbance in liver function (jaundice)
• signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers (agranulocytosis) contact your doctor straight away for a blood test.
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 and unconsciousness. In very rare cases these can be signs of serotonin syndrome.

Some side effects are more likely to occur than others. The possible side effects of Mirtazapine Orodispersible tablets are listed below and can be divided as:

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
• constipation
• vomiting
• 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
• memory problems, which in most cases resolved when treatment was stopped.

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

Stop taking Mirtazapine Orodispersible tablets and tell your doctor straight away.

Rare (may affect 1 in 1,000 people)
• aggression
• inflamed pancreas causing abdominal pain, swelling or tenderness (pancreatitis)
• muscle twitching or contractions (myoclonus)
• Inflamed or injured liver cells (elevations in serum transaminase activities)

Stop taking Mirtazapine Orodispersible tablets and tell your doctor straight away.

Not known (frequency cannot be estimated from the available data)
• abnormal sensations in the mouth (oral paraesthesia)
• swelling in the mouth (mouth oedema)
• Swelling due to excessive fluid accumulation at a specific site (localized oedema)
• fluid accumulation that affects the whole body (generalized oedema)
• increased salivation
• sleepwalking (Somnambulism)
• impaired speech (dysarthria)
• abnormal muscle breakdown (Rhabdomyolysis)
• hyponatraemia
• inappropriate anti-diuretic hormone secretion

Other possible side effects with Mirtazapine Orodispersible tablets are:
Increased creatine kinase blood levels, difficulty in passing urine and muscle pain, stiffness and/or weakness and darkening or discoloration of the urine.

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. 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 Mirtazapine Orodispersible Tablets

Keep this medicine out of the sight and reach of children.

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

Do not use this medicine after the expiry date which is stated on the carton or foil after EXP. The expiry date refers to the last day of that month.
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.

Contents of the pack and other information What Mirtazapine Orodispersible Tablets contains

•The active substance is Mirtazapine. Each tablet contains either 15mg, 30mg and 45mg of the active ingredient Mirtazapine.

•The other ingredients are mannitol, microcrystallincellulose, crospovidone, hydroxylpropyl cellulose, magnesium carbonate heavy, silica colloidal anhydrous, L-methionine, magnesium stearate, guar gum, aspartame (E951), orange flavour.

What Mirtazapine Orodispersible Tablets looks like and contents of the pack

Each Mirtazapine Orodispersible Tablet is a white, round, biconvex, uncoated tablet with the following markings:

15mg orodispersible tablets -M1

30mg orodispersible tablets -M2

45mg orodispersible tablets -M4

The tablets are supplied in blister packs of 30 Tablets.

Marketing Authorisation holder and manufacturer

Marketing Authorisation Holder:

Focus Pharmaceuticals Limited, Dashwood House, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

Manufactured by:

Actavis Limited, BLB016, Bulebel Industrial Estate,
Zejtun ZTN 3000 Malta.

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