1. WHAT MIRTAZAPINE TABLETS ARE AND WHAT THEY ARE USED FOR

Mirtazapine is one of a group of medicines called antidepressants. Mirtazapine tablets are used to treat depressive illness in adults.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MIRTAZAPINE TABLETS

Children and adolescents

Mirtazapine 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 Mirtazapine for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Mirtazapine 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.

3. HOW TO TAKE MIRTAZAPINE TABLETS

Mirtazapine 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 Mirtazapine for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Mirtazapine 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.

4. POSSIBLE SIDE EFFECTS

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.

Also take special care with Mirtazapine tablets:

• if you have, or have ever had one of the following conditions:
  → Tell your doctor about these conditions before taking Mirtazapine tablets, if not done previously:
  - seizures (epilepsy). If you develop seizures or your seizures become more frequent, stop taking Mirtazapine and contact your doctor immediately;
  - liver disease, including jaundice. If jaundice occurs, stop taking Mirtazapine 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/overactive and depressed mood). If you start feeling elated or over-excited, stop taking Mirtazapine and contact your doctor immediately;

5. HOW TO STORE MIRTAZAPINE TABLETS

Store out of the sight and reach of children.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Mirtazapine tablets contain

The active substance is Mirtazapine. Each tablet contains 15 mg, 30 mg or 45 mg Mirtazapine. The other ingredients are lactose monohydrate, maize starch, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium stearate, silica colloidal anhydrous, hypromellose (E464) and titanium dioxide (E171).

The 15 mg tablets also contain yellow iron oxide (E172), red iron oxide (E172) and black iron oxide (E172).

What Mirtazapine tablets look like and contents of the pack

Mirtazapine 15 mg tablets: Yellow, biconvex, capsule shaped film coated tablets with score line on one side and 15 debossed on other side.

Mirtazapine 30 mg tablets: Reddish brown, biconvex, capsule shaped film coated tablets with score line on one side and 30 debossed on other side.

Mirtazapine 45 mg tablets: White, biconvex, capsule shaped film coated tablets plain on one side and 45 debossed on other side.

Mirtazapine 15, 30, 45 mg tablets are available in PVC coated and PVdC blister packs of 10/14/28/30/40/50/56/60/70/84/90/100/200/250/500 tablets. Not all pack sizes may be marketed.

What is in this leaflet

- If you are a young adult. Information from clinical trials has shown an increased risk of aggressive, oppositional behaviour and anger when they take this class of medicines. Despite this, your doctor may prescribe Mirtazapine for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Mirtazapine 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.

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. In addition, significant weight gain has been observed in this age category more often when treated with Mirtazapine compared with adults.

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 2 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.

To Listen to or request a copy of this leaflet in Braille, large print or audio please call, 02088311580 (UK only)

Please be ready to give the following information:

Product name

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<tr>
<th>Mirtazapine 15mg Tablets</th>
<th>Mirtazapine 30mg Tablets</th>
<th>Mirtazapine 45mg Tablets</th>
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<td>PL 21880/0053</td>
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Marketing Authorisation Holder and Manufacturer

MEDRECH PLC
Warwick House, Plane Tree Crescent, Feltham TW13 7HF, UK
E-mail: info@medreich.co.uk

121XXXX-V1
• diabetes (you may need to adjust your dose of insulin or other antidiabetic medicines);
• liver disease, such as increased pressure in the eye (glaucoma);
• difficulty in passing water (urinating), which might be caused by an enlarged prostate;
• Certain kinds of heart conditions that may change your heart rhythm, a recent heart attack, heart failure, or take certain medicines that may affect heart’s rhythm.
  • if you develop signs of infection such as inapplicable high fever, sore throat and mouth ulcers. 
    → Stop taking Mirtazapine 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 tablets

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

Do not take Mirtazapine tablets in combination with:
• monoamine oxidase inhibitors (MAO inhibitors). Also, do not take Mirtazapine during the two weeks after you have stopped taking MAO inhibitors. If you stop taking Mirtazapine, 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 tablets in combination with:
• antidepressants such as SSRIs, venlafaxine and L-tyrphostin, or triptans (used to treat migraine), tramadol (a pain-killer), linezolid (an antibiotic), lithium (used to treat some psychiatric conditions), methystine blue (used to treat high levels of methemoglobin in the blood) and St. John’s Wort = Hypericum perforatum preparations (a herbal remedy for depression). In very rare cases Mirtazapine alone or the combination of Mirtazapine with these medicines, can lead to a so-called serotonin syndrome. Some of the symptoms of this syndrome are: inapplicable fever, sweating, increased heart rate, diarrhoea, (uncontrollable) muscle contractions, shivering, overactive reflexes, restlessness, memory loss, confusion 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, or when use of nefazodone is stopped, to increase the dose of Mirtazapine 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;

Examples of these medicines have Mirtazapine 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 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, or when these medicines are stopped, to increase the dose of Mirtazapine again.
• medicines for epilepsy such as carbamazepine and phenytoin;
• medicines for tuberculosis such as rifampicin.

In combination with Mirtazapine 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, or when these medicines are stopped, to lower the dose of Mirtazapine 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.

Mirtazapine tablets with food, drink and alcohol

You may get drowsy if you drink alcohol while taking Mirtazapine. You are advised not to drink any alcohol. You can take Mirtazapine 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 administration to pregnant women does not indicate an increased risk. However, caution should be exercised when used during pregnancy.

If you take Mirtazapine 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 (PPPHN), 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.

Driving and using machines: Mirtazapine can affect your concentration or alertness. Make sure these abilities are not affected before operating motor vehicles or machinery.

Prescribed Mirtazapine for a patient under 18 years make sure the concentration and alertness is not affected before participating in traffic (e.g. on bicycle).

Mirtazapine tablets contain lactose

Mirtazapine film-coated tablet contains 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 MIRTAZAPINE TABLETS
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 15 or 30 mg 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 adopt the dose.

When to take Mirtazapine tablets

→ Take Mirtazapine tablets at the same time each day.

It is best to take Mirtazapine tablets for a day or two before you go to bed. However your doctor may suggest to split your dose of Mirtazapine 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.

How to take Mirtazapine tablets:
Take your tablets orally. Swallow your prescribed dose of Mirtazapine tablets without chewing, with some water or juice. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

When can you expect to start feeling better

Usually Mirtazapine 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:
→ 2 to 4 weeks after you have started taking Mirtazapine, 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 until symptoms of depression have disappeared for 4 to 6 months.

If you take more Mirtazapine tablets than you should

If you or someone else have taken too much Mirtazapine, call a doctor straight away.

There 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 tablets

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 dose at 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 tablets

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

Possible side effects of Mirtazapine tablets are:

Very common (may affect more than 1 in 10 people):
• increase in appetite and weight gain
• headache
• increase in appetite and weight gain
  • dry mouth

Common (may affect up to 1 in 10 people):
• lethargy
• shakiness or tremor
• diaphoresis
• rash or skin eruptions (exanthema)
• tiredness
• confusion
• sleeping problems
• pain in your joints (arthralgia) or muscles (myalgia)
• sleeping problems
  • feeling dizzy or faint when you stand up suddenly (orthostatic hypotension)
• fatness (symptoms of increased fatness are often caused by fluid retention (oedema)

Uncommon (may affect up to 1 in 100 people):
• restless legs
• low blood pressure
• feeling agitated
• feeling elated or emotionally ‘high’ (mania)
• sensitivity of numbness in the mouth (oral hypoaesthesia)
• unusual or severely tingling in the skin (e.g. burning, stinging, tickling or tingling (parasthesia)
• extreme tiredness
• rashes or blisters
• sudden swelling in ankles or feet
• increase in appetite and weight gain
• dry mouth
• rash
• jaundice
• vomiting
• feeling anxious
• constipation
• abdominal pain and nausea; this may suggest inflammation of the pancreas (pancreatitis)
• Yellow colouring of eyes or skin; this may suggest disturbance in liver function (jaundice)