Mirtazapine tablets are used to treat depressive illness in adults.

Do not take Mirtazapine tablets:
- If you are allergic (hypersensitive) to mirtazapine or any of the other ingredients of this medicine (listed in section 6). If so, you must talk to your doctor as soon as you can before taking Mirtazapine tablets.
- If you are pregnant or intend to become pregnant.
- If you are breastfeeding.
- If you are an elderly person. You could be more sensitive to the side-effects of medicines. Despite this, your doctor may prescribe Mirtazapine tablets for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Mirtazapine tablets for a patient under 18 years make sure the concentration and alertness level of the tablets are appropriate for the person's age and weight.

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.

If you are depressed you can sometimes have thoughts of harming or killing yourself. These thoughts may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

Take care when taking Mirtazapine in combination with:
- Other medicines and Mirtazapine tablets. In combination with these medicines can reduce 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 severe pain such as codeine.
- Medicines for anxiety or insomnia such as zopiclone.
- Medicines for allergic reactions such as chlorphenamine.
- Medicines for severe pain such as morphine.
- Medicines for epilepsy such as carbamazepine and phenytoin.
- Medicines for anti-infective (bacterial infections such as penicillin).
- Medicines for fungal infections such as ketoconazole and itraconazole.
- Medicines for HIV/AIDS (such as protease inhibitors) and drugs for stomach ulcers (such as cimetidine).
- Medicines for schizophrenia such as olanzapine.
- Medicines for allergies such as cetirizine.
- Medicines for severe pain such as morphine.

Mirtazapine tablets contain Lactose (such as lactose monohydrate and lactose dihydrate). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Driving and using machines
You may get drowsy if you drink alcohol while you are taking Mirtazapine. You are advised not to drink any alcohol. You can take Mirtazapine 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 administration to pregnant women does not indicate an increased risk. However, caution should be exercised in the first 3 months of pregnancy.

If you use Mirtazapine tablets until, or shortly before birth, your baby should be supervised by a doctor immediately.

Driving and using machines
Mirtazapine tablets can affect your concentration or alertness. Make sure these abilities are not affected before you drive or operate machinery. If you have ever developed any severe skin reactions, treatment with Mirtazapine tablets should not be restarted.

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 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, phenelzine, isocarboxazid (both are antidepressants) and selegiline (used for Parkinson’s disease).
When to take Mirtazapine tablets

→ Take Mirtazapine tablets at the same time each day. It is best to take Mirtazapine tablets as a single dose 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. Take your tablets orally. Swallow your prescribed dose of Mirtazapine tablets without chewing, with some water or juice.

When you should expect to feel feeling better

Usually Mirtazapine tablets will start working after 1 to 2 weeks and after 2 to 4 weeks you may find you feel better.

It is important that, during the first few weeks of the treatment, you talk with your doctor about the effects of Mirtazapine tablets.

→ 2 to 4 weeks after you have started taking Mirtazapine 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 another 2 to 4 weeks. Usually you will need to take Mirtazapine tablets until your symptoms of depression have disappeared for 4 to 6 months.

If you take more Mirtazapine tablets than you should

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

The most likely signs of an overdose of Mirtazapine 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 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 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 tablets

→ Only stop taking Mirtazapine tablets in consultation with your doctor.

If you stop too early, your depression may 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 tablets, even when your depression has lifted. If you suddenly stop taking Mirtazapine 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.

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)

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

• signs of infection such as sudden unexplained high fever, sore throat and mouth ulcers (stomatitis). In rare cases mirtazapine can cause sepsis in the production of white blood cells (granulocytopenia). In rare cases mirtazapine can cause a temporary shortage of white blood cells (granulocytopenia). In rare cases mirtazapine can cause sepsis in the production of red blood cells (erythroblastosis), as well as blood platelets (thrombocytopenia). A shortage of blood platelets (thrombocytopenia) or an increase in the number of white blood cells (eosinophilia).

• aplastic 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.

• thoughts of harming or killing yourself

• reddish patches on the trunk which are target-like macules or circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitalia and eyes. These severe 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).

Other possible side effects with mirtazapine are:

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

• increase in appetite and weight gain

• dizziness or drowsiness

• shaking or tremor

• nausea

• diarrhoea

• vomiting

• rash or skin eruptions (exanthemat)

• 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, tingling or itching (paresthesia)

• restless legs

• fainting (syncope)

• sensations of numbness in the mouth (oral hypoesthesia)

• 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)

• aggression

• abdominal pain and nausea, this may suggest inflammation of the pancreas (pancreatitis)

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

• abnormal sensations in the mouth (oral paresthesia)

• swelling in the mouth (mouth oedema), increase in saliva secretion or watery mouth

• swelling throughout the body (generalised oedema)

• localized swelling

• hypoaesthesia

• inappropriate anti-diuretic hormone secretion

• speech disorder

• sleepwalking (somnambulism)

• blisters of the skin (dermatitis bullosa)

• Skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) called erythema multiforme

• increased creatinine kinase blood levels

• difficulty in passing urine (urinary retention)

• muscle pain, stiffness and/or weakness, darkening or discolouration of the urine (rhabdomyolysis)

• increased procalcitonin hormone levels in blood (hyperprocalcitoninaemia), including symptoms of enlarged breasts and/or milk niple 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 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 Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

In case of overdose of Mirtazapine tablets

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

This medicinal product does not require any special storage conditions.

Store in the original package.

Do not use this medicine 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.

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 to protect the environment.

5. Contents of the pack and other information

What Mirtazapine tablets contain

The active substance is Mirtazapine. Each film coated tablet contains 15, 30 or 45 mg Mirtazapine.

• The other ingredients are lactose monohydrate, maize starch, hydroxypropyl cellulose, low substituted hydroxypropyl cellulose, magnesium stearate (E476), silica colloidal anhydrous, hypromellose (E464) and titanium dioxide (E 171).

The 15 mg tablets also contain yellow iron oxide (E 172).

The 30 mg tablets also contain yellow iron oxide (E 172) and black iron oxide (E172).

What Mirtazapine tablet looks like and contents of the pack

Mirtazapine 15 mg tablets are yellow, biconvex capsule shaped film coated tablets debossed with a score line in between “1” and “5” on one side and “MF” debossed on the other side.

Mirtazapine 30 mg tablets are reddish brown biconvex capsule shaped film coated tablets debossed with a score line in between “3” and “0” on one side and “MF” debossed on the other side.

Mirtazapine 45 mg tablets are white, biconvex capsule shaped film coated tablets with “45” debossed on one side and “MF” debossed on the other side.

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

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Mipharm Limited
Aires Block, Odyssey Business Park
West End Road
Ruislip HA4 6QD
United Kingdom

Manufacturer

Mipharm Limited
Aires, Odyssey Business Park
West End Road, South Ruislip
HA4 6QD, United Kingdom.
or

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far, Birzebbugia, BBG 3000.

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