WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET

Mirtazapine (15mg, 30mg)

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What WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET is used for
WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET is one of a group of medicines called **antidepressants**.
WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET is used to treat depressive illness.

How WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET works WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET belongs to the group of medicines known as antidepressants that alleviate depressed mood, a characteristic of depression. Depression is a disturbance in emotional life. During depression changes in the brain take place. Nerve cells in the brain communicate with each other by means of chemical substances. In cases of depression the normal supply of these substances is reduced. Antidepressants can restore these deficiencies and re-establish the normal function of the brain. In general, it may take two to four weeks of oral treatment before you experience an improvement.

Before you take WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET

- *When you must not take it*

Do not take WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET:
• if you are allergic (hypersensitive) to mirtazapine or any of the other ingredients of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET. If so, you must talk to your doctor as soon as you can before taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET.
• if you are taking or have recently taken (within the last two weeks) medicines called monoamine oxidase inhibitors (MAO-Is).

- *Before you start to take it*

Use in children and adolescents under 18 years of age
WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET should normally not be used for children and adolescents under 18 years as efficacy was not demonstrated in two short-term clinical trials and because of safety concerns.

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 behavior and anger) when they take this class of medicines. Despite this, your doctor may prescribe WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 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 WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioral development of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 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 behavior 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 straightaway.

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 behavior.

Also take special care with WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET
• if you have or have ever had one of the following conditions.
→ Tell your doctor about these conditions before taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET, if not done previously.
- **seizures** (epilepsy). If you develop seizures or your seizures become more frequent, stop taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET and contact your doctor immediately;
- **liver disease**, including jaundice. If jaundice occurs, stop taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 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 straightaway;
- **manic depression** (alternating periods of feeling elated/overactivity and depressed mood). If you start feeling elated or over-excited, stop taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 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;
- **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 WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 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.

- *Taking other medicines*

Tell your docor or pharmacist if you are taking (or plan to take) any of the medicines in the following list. Please also tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Do not take WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET in combination with:
• **monoamine oxidase inhibitors** (MAO inhibitors). Also, do not take WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET during the two weeks after you have stopped taking MAO

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inhibitors. If you stop taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET, 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 WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 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. Johns Wort – Hypericum perforatum preparations** (a herbal remedy for depression). In very rare cases WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET alone or the combination of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 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, diarrhea, (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 WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET in your blood. Inform your doctor if you are using this medicine. It might be needed to lower the dose of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET, or when use of nefazodone is stopped, to increase the dose of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 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 WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 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 WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET these medicines can increase the amount of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET in your blood.

Inform your doctor if you are using these medicines. It might be needed to lower the dose of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET, or when these medicines are stopped, to increase the dose of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET again.

• **medicines for epilepsy** such as carbamazepine and phenytoin;

• **medicines for tuberculosis** such as rifampicin.

In combination with WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET these medicines can reduce the amount of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET in your blood. Inform your doctor if you are using these medicines. It might be needed to increase the dose of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET, or when these medicines are stopped to lower the dose of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET again.

• **medicines to prevent blood clotting** such as warfarin.

WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 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 anti-psychotics.

How to take WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET

Always take WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET exactly as your doctor or pharmacist tells you to. You should check with your doctor or pharmacist if you are not sure.

- *How much to take*

The usual starting dose is 15 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). However, if you are an elderly person or if you have renal or liver disease, your doctor may adapt the dose.

- *When to take it*

Take WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET at the same time each day. It is best to take WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET as a single dose before you go to bed. However, your doctor may suggest you to split your dose of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET – 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 it*

Take your tablets orally.

Take out the WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET with dry hands and place it on the tongue.

It will rapidly disintegrate and can be swallowed without water.

- *How long to take it*

Keep taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET until your doctor tells you to stop.

When can you expect to start feeling better

Usually, WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 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 WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET:

→ 2 to 4 weeks after you have started taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET, 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 WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET until your symptoms of depression have disappeared for at least 6 months.

- *If you forget to take it*

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

• If you have forgotten to take your dose of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET, do not take the missed 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 WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET

→ Only stop taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET in consultation with your doctor.

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

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

Do not suddenly stop taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET, even when your depression has lifted. If you suddenly stop taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 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 product, ask your doctor or pharmacist.

- *If you take too much (overdose)*

If you or someone else has taken too much WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET, call a doctor straightaway.
The most likely signs of an overdose of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET (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.

While you are taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET

- *Things you must do*

Tell the doctor treating you what medicine(s) you are taking. Always carry a medical information card showing which medicine(s) you are using. This can be very important if you are involved in an accident.

Make sure that other people you live with or who look after you also read this information leaflet.
If you have any further questions, ask your doctor or pharmacist.

- *Things you must not do*

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.

- *Things to be careful of*

Taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET with food and alcohol
You may get drowsy if you drink alcohol while you are taking WHAN IN MIRTAZAPINE ORODISPERSIBLE
TABLET. You are advised not to drink any alcohol. You can take WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET with or without food.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.
Limited experience with WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET administration to pregnant women does not indicate an increased risk.
However, caution should be exercised when used during pregnancy.

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

Ask your doctor whether you can breast- feed, while taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET.

Driving and using machines
WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET can affect your concentration or alertness. Make sure these abilities are not affected before you drive or operate machinery.

Important information about some of the ingredients of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET

WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET contains aspartame, a source of phenylalanine. It may be harmful for people with phenylketonuria.

Side effects
Like all medicines, WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET can cause side effects, although not everybody gets these side effects. Some side effects are more likely to occur than others. The possible side effects of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET are listed below and can be divided as:

Very common (affects more than 1 user in 10):
- increase in appetite and weight gain
- drowsiness or sleepiness
- headache
- dry mouth

Common (affects 1 to 10 users in 100):
- 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 (edema)
- tiredness
- vivid dreams
- confusion
- feeling anxious
- sleeping problems
- memory problems

Uncommon (affects 1 to 10 users in 1000):
- feeling elated or emotionally 'high' (mania)
  → Stop taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET and tell your doctor straight away.
- abnormal sensation in the skin e.g. burning, stinging, tickling or tingling (paresthesia)
- restless legs
- fainting (syncope)
- sensations of numbness in the mouth (oral hypoesthesia)
- low blood pressure
- nightmares
- feeling agitated
- hallucinations
- urge to move

Rare (affects 1 to 10 users in 10,000):
- yellow discoloration of eyes or skin; this may suggest disturbance in liver function (jaundice)
  → Stop taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET and tell your doctor straight away.
- muscle twitching or contractions (myoclonus)
- aggression
- abdominal pain and nausea; this may suggest inflammation of the pancreas (pancreatitis)

Not known (cannot be estimated from available data):
- signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers (agranulocytosis)

→ Stop taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET and contact your doctor straight away for a blood test.
In rare cases WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET can cause disturbances in the production of blood cells (bone marrow depression). Some people become less resistant to infection because WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET can cause a temporary shortage of white blood cells (granulocytopenia). In rare cases WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET can also cause a shortage of red and white blood cells, as well as blood platelets (aplastic anemia), a shortage of in

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the number of white blood cells (eosinophilia).
• epileptic attack (convulsions)
→ Stop taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET and tell your doctor straight away.
• 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.
→ Stop taking WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET and tell your doctor straight away.
• thoughts of harming or killing yourself
→ Contact your doctor or go to a hospital straight away.
• abnormal sensations in the mouth (oral paresthesia)
• swelling in the mouth (mouth edema)
• swelling throughout the body (generalized oedema)
• localized swelling
• hyponatremia
• severe skin reactions (Stevens-Johnson syndrome, dermatitis bullous, erythema multiforme, toxic epidermal necrolysis)
• Serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS may appear initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature and enlarged lymph nodes.
• speech disorder
• increased creatine kinase blood levels
• difficulty in passing urine (urinary retention)
• muscle pain, stiffness and/or weakness, darkening or discolouration of the urine (rhabdomyolysis)
• increased prolactin hormone levels in blood (hyperprolactinemia, including symptoms such as enlarged breasts and/or milky nipple discharge)
• sleepwalking
• prolonged painful erection of the penis

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers →Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET

- *Storage*

Keep out of the reach and sight of children.

Do not use WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET after the expiry date which is stated on the carton and the 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.

- *Disposal*

Medicines should not be disposed of via waste water or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- *What it looks like*

WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 15 mg are round, white, Standard beveled-edge tablets coded with 'Z2' on one side.

WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET 30 mg are round, white, standard beveled- edge tablets coded with 'Z1' on one side.

The orodispersible tablets are packed in a Alu-Alu unit dose blister.

Pack size: blister packs of 3 x 10 tablets (30 Tablets)

- *Ingredients*

Active ingredient:

WHAN IN MIRTAZAPINE ORODISPERSIBLE TABLET contains 15 mg or 30 mg mirtazapine per orodispersible tablet.

Inactive ingredients :

Silicified microcrystalline cellulose, Pearlitol Flash, Calcium Silicate, crospovidone, Aspartame, Steviol Glycoside, orange flavor, Magnesium Stearate

- *MAL number:*

MALxxxxxxxxxx(15 MG)
MALxxxxxxxxxx(30 MG)

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