

Package leaflet: information for the user

Mirtazapine Teva 15, 30 & 45 mg 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 of the 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 Teva is and what it is used for
2. What you need to know before you take Mirtazapine Teva
3. How to take Mirtazapine Teva
4. Possible side effects
5. How to store Mirtazapine Teva
6. Content of the pack and other information

1. What Mirtazapine Teva is and what it is used for

- Mirtazapine Teva is one of a group of medicines called **antidepressants**.
- Mirtazapine Teva is used to treat depressive illness.
- You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Mirtazapine Teva

Do not take Mirtazapine Teva

- If you are **allergic** (hypersensitive) to Mirtazapine or any of the other ingredients of . If so, you must talk to your doctor as soon as you can before taking Mirtazapine Teva.
- If you are taking or have recently taken (within the last two weeks) medicines called monoamine oxidase inhibitors (MAO-Is).

Take special care with Mirtazapine Teva

Warnings and precautions

Talk to your doctor before taking Mirtazapine Teva

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.

Also take care with Mirtazapine Teva:

- If you have, or have ever had one of the following conditions:
 - Tell your doctor about these conditions before taking Mirtazapine Teva, if not done previously.
 - **seizures** (epilepsy). If you develop seizures or your seizures become more frequent, stop taking Mirtazapine Teva and contact your doctor immediately.
 - **liver disease**, including jaundice. If jaundice occurs, stop taking Mirtazapine Teva 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 Teva 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 Teva 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.

Children and adolescents

Mirtazapine Teva 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 Teva for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Mirtazapine Teva 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 Teva. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Mirtazapine Teva 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 Teva compared with adults.

Other medicines and Mirtazapine Teva

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

Do not take Mirtazapine Teva in combination with:

- **monoamine oxidase inhibitors** (MAO inhibitors). Also, do not take Mirtazapine Teva during the two weeks after you have stopped taking MAO inhibitors. If you stop taking Mirtazapine Teva, 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 Teva 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) and **St. John's Wort – *Hypericum perforatum* preparations** (a herbal remedy for depression) :In very rare cases Mirtazapine Teva alone or the combination of Mirtazapine Teva 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 Teva in your blood. Inform your doctor if you are using this medicine. It might be needed to lower the dose of Mirtazapine Teva, or when use of nefazodone is stopped, to increase the dose of Mirtazapine Teva again.
- **Medicines for anxiety and 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 Teva 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):
in combination with Mirtazapine Teva these medicines can increase the amount of Mirtazapine Teva in your blood. Inform your doctor if you are using these medicines. It might be needed to lower the dose of Mirtazapine Teva, or when these medicines are stopped, to increase the dose of Mirtazapine Teva again.
- **Medicines for epilepsy** such as carbamazepine or phenytoin,
Medicines for tuberculosis such as rifampicin: in combination with Mirtazapine Teva these medicines can reduce the amount of Mirtazapine Teva in your blood. Inform your doctor if you are using these medicines. It might be needed to increase the dose of Mirtazapine Teva, or when these medicines are stopped to lower the dose of Mirtazapine Teva again.
- **Medicines to prevent blood clotting** such as warfarin: Mirtazapine Teva 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.
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Mirtazapine Teva with food, drink and alcohol

You may get drowsy if you drink alcohol while you are taking Mirtazapine Teva. You are advised not to drink any alcohol.

You can take Mirtazapine Teva with or without food.

Pregnancy and breast-feeding

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

Limited experience with Mirtazapine Teva administration to pregnant women does not indicate an increased risk. However, caution should be exercised when used during pregnancy. If you are taking and you become pregnant or you plan to get pregnant, ask your doctor whether you may continue taking Mirtazapine Teva. If you use Mirtazapine Teva 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 < >. When taken during pregnancy, similar

drugs (SSRIs) may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (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 Teva. 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.

Driving and using machines

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

Mirtazapine Teva contains aspartame

Aspartame contains a source of phenylalanine. May be harmful for people with phenylketonuria.

3. How to take Mirtazapine Teva

Always take exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is between 15 mg and 45 mg

The usual 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 adapt the dose.

When to take Mirtazapine Teva

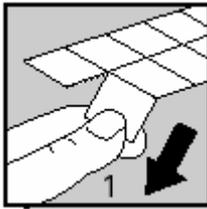
→ Take Mirtazapine Teva at the same time each day.

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

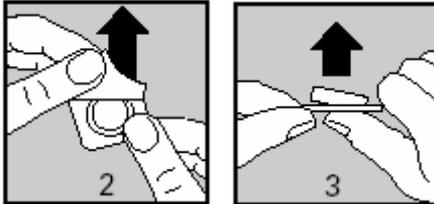
Take the orodispersible tablet as follows

Take your tablets orally.

- Do not crush the orodispersible tablet: in order to prevent crushing the orodispersible tablet, do not push against the tablet pocket
- Tear off one tablet pocket.
Each blister contains six tablet pockets, which are separated by perforations. Tear off one tablet pocket along the dotted lines (Figure 1):



- Peel off the lid.
Carefully peel off the lidding foil, starting in the corner indicated by the arrow (Figure 2):



- Take out the orodispersible tablet.
Take out the orodispersible tablet with dry hands (Figure 3) and place it on the tongue. It will rapidly disintegrate and can be swallowed with or without water.

When can you expect to start feeling better

Usually Mirtazapine Teva 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 Teva:

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

If you take more Mirtazapine Teva than you should

- If you or someone else have taken too much Mirtazapine Teva, call a doctor straight away. The most likely signs of an overdose of Mirtazapine Teva (without other medicines or alcohol) are **drowsiness, disorientation and increased heart rate**.

If you forget to take Mirtazapine Teva

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

- If you have forgotten to take your dose of Mirtazapine Teva, 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 Mirtazapine Teva

- Only stop taking Mirtazapine Teva 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 Teva, even when your depression has lifted. If you suddenly stop taking Mirtazapine Teva 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, can cause side effects, although not everybody gets them.

Stop taking Mirtazapine Teva and tell your doctor straight away if you develop any of the following side effects:

- 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). Your doctor should order a blood test.
In rare cases Mirtazapine Teva can cause disturbances in the production of blood cells (bone marrow depression). Some people become less resistant to infection because Mirtazapine Teva can cause a temporary shortage of white blood cells (granulocytopenia). In rare cases Mirtazapine Teva 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.
- Thoughts of harming or killing yourself. Contact your doctor or go to a hospital straight away.
- Steven Johnson's syndrome and Toxic epidermal necrolysis - very rare but very serious side effects. If you experience any of the following side effects tell your doctor or nurse straight away:
 - skin peeling
 - sores on the mucous membranes
 - skin rash,

Other possible side effects

Other possible side effects of Mirtazapine Teva are listed below. Some side effects are more likely to occur than others:

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, tiredness
- Nausea, diarrhoea, 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)
- 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, urge to move, fainting (syncope)
- Sensations of numbness in the mouth (oral hypoaesthesia)
- Low blood pressure
- Nightmares, feeling agitated, hallucinations

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

- Muscle twitching or contractions (myoclonus)
- Aggression
- Inflammation of the pancreas

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

- Erythema multiforme, a skin disease characterised by itchy pink-red blotches starting on your feet and hands
- Blisters full of fluid (dermatitis bullous)
- Increased salivation
- Sleep walking
- Distorted speech (dysarthria)
- Abnormal sensations in the mouth (oral paraesthesia)
- Swelling in the mouth (mouth oedema)
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- Hyponatraemia
- Inappropriate anti-diuretic hormone secretion
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If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Mirtazapine Teva

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

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

This medicinal product does not require any special storage conditions. Do not transfer to another container.

Do not throw away any medicine 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.

6. FURTHER INFORMATION

What Mirtazapine Teva contains

- The active substance is Mirtazapine Teva. Each tablet contains 15, 30 or 45 mg Mirtazapine Teva.
- Other ingredients are xylitol, precipitated silica, basic butylated methacrylate copolymer, crospovidone, aspartame, orange flavour, mannitol, magnesium stearate.

What Mirtazapine Teva looks like and contents of the pack

- The 15 mg tablets are round, white, bevelled edge tablets marked with number "93" on one side and with number "7303" on the other.
- The 30 mg tablets are round, white, bevelled edge tablets marked with number "93" on one side and with number "7304" on the other
- The 45 mg tablets are round, white, bevelled edge tablets marked with number "93" on one side and with number "7305" on the other
- The 15 mg tablets are available in pack sizes of 6, 12, 18, 28, 30, 48, 50, 60, 90, 96, 100, 200 and 500 tablets.
- The 30 mg tablets are available in pack sizes of 6, 12, 18, 28, 30, 48, 50, 60, 90, 96, 100, 180, 200 and 500 tablets.
- The 45 mg tablets are available in pack sizes of 18, 28, 30, 48, 50, 60, 90, 96, 100, 180, 200 and 500 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is

Teva Pharma B.V.,
Swensweg 5,
2031GA Haarlem,
The Netherlands.

The company responsible for manufacture is

Teva UK Limited,
Eastbourne,
BN22 9AG,
United Kingdom.

Pharmachemie B.V.
Swensweg 5
Postbus 552
2003 RN Haarlem
Netherlands

Teva Santé
Rue Bellocier
89107 Sens
France

TEVA Pharmaceutical Works Ltd.
13 Pallagi Street
Debrecen H-4042

Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

- Belgium: Mirtzapine Teva TEVA 15 mg Orodispergeerbare tabletten, Mirtzapine Teva TEVA 30 mg Orodispergeerbare tabletten, Mirtzapine Teva TEVA 45 mg Orodispergeerbare tabletten
- Denmark: Mirtazapin Teva,
- Hungary: Mizapin Sol 15 mg szájban diszpergálódó tableta, Mizapin Sol 30 mg szájban diszpergálódó tableta, Mizapin Sol 45 mg szájban diszpergálódó tableta
- Ireland: Mirtzapine Teva Teva 15 mg Orodispersible tablet, Mirtzapine Teva Teva 30 mg Orodispersible tablet, Mirtzapine Teva Teva 45 mg Orodispersible tablet
- Italy: Mirtazapina Teva 15 mg Compresse orodispersibili, Mirtazapina Teva 30 mg Compresse orodispersibili, Mirtazapina Teva 45 mg Compresse orodispersibili
- Germany: Mirtazapin-TEVA® 15 mg Schmelztabletten, Mirtazapin-TEVA® 30 mg Schmelztabletten, Mirtazapin-TEVA® 45 mg Schmelztabletten
- Netherlands: Mirtzapine Teva disp 15 PCH, orodispergeerbare tabletten, Mirtzapine Teva disp 30 PCH, orodispergeerbare tabletten, Mirtzapine Teva disp 45 PCH, orodispergeerbare tabletten
- Norway: Mirtazapin Teva 15 mg smeltetabletter, Mirtazapin Teva 30 mg smeltetabletter, Mirtazapin Teva 45 mg smeltetabletter
- Portugal: Mirtazapina Teva 15 mg Comprimidos orodispersíveis, Mirtazapina Teva 30 mg Comprimidos orodispersíveis, Mirtazapina Teva 45 mg Comprimidos orodispersíveis
- Spain: Mirtazapina TEVA 15 mg Comprimidos bucodispersables EFG, Mirtazapina TEVA 30 mg Comprimidos bucodispersables EFG,
- Sweden: Mirtazapin Teva 15 mg munsönderfallande tablett, Mirtazapin Teva 30 mg munsönderfallande tablett, Mirtazapin Teva 45 mg munsönderfallande tablett
- United Kingdom: Mirtzapine Teva 15 mg Orodispersible tablet, Mirtzapine Teva 30 mg Orodispersible tablet, Mirtzapine Teva 45 mg Orodispersible tablet

This leaflet was last revised in June 2015.