

ZISPIN® SolTab®

45 MG

orodispersible tablet

Mirtazapine

Read all of this leaflet carefully before you start taking this medicine.

- 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 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.

In this leaflet:

1. What Zispin SolTab is and what it is used for
2. Before you take Zispin SolTab
3. How to take Zispin SolTab
4. Possible side effects
5. How to store Zispin SolTab
6. Further information

1. What Zispin SolTab Is And What It Is Used For

Zispin SolTab is one of a group of medicines called **antidepressants**. Zispin SolTab is used to treat depressive illness.

2. Before You Take Zispin SolTab

Do not take Zispin SolTab

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

Take special care with Zispin SolTab

Use in children and adolescents under 18 years of age

Zispin SolTab should normally not be used for children and adolescents under 18 years. 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 Zispin SolTab for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Zispin SolTab 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 Zispin SolTab. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Zispin SolTab 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 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 special care with Zispin SolTab

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

- **monoamine oxidase inhibitors** (MAO inhibitors). Also, do not take Zispin SolTab during the two weeks after you have stopped taking MAO inhibitors. If you stop taking Zispin SolTab, 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 Zispin SolTab 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 Zispin SolTab alone or the combination of Zispin SolTab 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 Zispin SolTab in your blood. Inform your doctor if you are using this medicine. It might be needed to lower the dose of Zispin SolTab, or when use of nefazodone is stopped, to increase the dose of Zispin SolTab 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 Zispin SolTab 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 Zispin SolTab these medicines can increase the amount of Zispin SolTab in your blood. Inform your doctor if you are using these medicines. It might be needed to lower the dose of Zispin SolTab, or when these medicines are stopped, to increase the dose of Zispin SolTab again.
- **medicines for epilepsy** such as carbamazepine and phenytoin;
- **medicines for tuberculosis** such as rifampicin. In combination with Zispin SolTab these medicines can reduce the amount of Zispin SolTab in your blood. Inform your doctor if you are using these medicines. It might be needed to increase the dose of Zispin SolTab, or when these medicines are stopped to lower the dose of Zispin SolTab again.
- **medicines to prevent blood clotting** such as warfarin. Zispin SolTab 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.

Taking Zispin SolTab with food and drink

You may get drowsy if you drink alcohol while you are taking Zispin SolTab. You are advised not to drink any alcohol. You can take Zispin SolTab with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Limited experience with Zispin SolTab administration to pregnant women does not indicate an increased risk. However, caution should be exercised when used during pregnancy. If you are taking Zispin SolTab and you become pregnant or you plan to get pregnant, ask your doctor whether you may continue taking Zispin SolTab. If you use Zispin SolTab until, or shortly before birth, your baby should be supervised for possible adverse effects. Ask your doctor whether you can breast-feed, while taking Zispin SolTab.

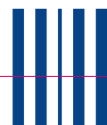
Driving and using machines

Zispin SolTab 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 Zispin SolTab

Zispin SolTab orodispersible tablets contain sugar spheres, containing sucrose. If you have been told by your doctor that you have an intolerance for some sugars, contact your doctor before taking this medicinal product. Zispin SolTab orodispersible tablets contain aspartame, a source of phenylalanine. May be harmful for people with phenylketonuria.

now turn over ➔



3. How To Take Zispin SolTab

Always take Zispin SolTab 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 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 Zispin SolTab

→Take Zispin SolTab at the same time each day. It is best to take Zispin SolTab as a single dose before you go to bed. However your doctor may suggest to split your dose of Zispin SolTab – 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.

1. Do not crush the orodispersible tablet

In order to prevent crushing the orodispersible tablet, do not push against the tablet pocket (Figure A).



Fig. A.

2. 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).

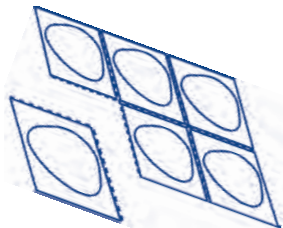


Fig. 1.

3. Peel off the lid

Carefully peel off the lidding foil, starting in the corner indicated by the arrow (Figures 2 and 3).



Fig. 2.

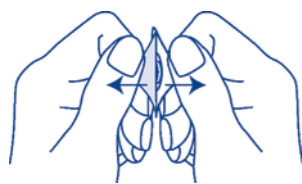


Fig. 3.

4. Take out the orodispersible tablet

Take out the orodispersible tablet with dry hands and place it on the tongue. (Figure 4).



Fig. 4.

It will rapidly disintegrate and can be swallowed without water.

When can you expect to start feeling better

Usually Zispin SolTab 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 Zispin SolTab:

→2 to 4 weeks after you have started taking Zispin SolTab, 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 Zispin SolTab until your symptoms of depression have disappeared for 4 to 6 months.

If you take more Zispin SolTab than you should

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

If you forget to take Zispin SolTab

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

- If you have forgotten to take your dose of Zispin SolTab, 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 Zispin SolTab

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

4. Possible Side Effects

Like all medicines, Zispin SolTab 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 Zispin SolTab are listed below and can be divided as:

- Very common: affects more than 1 user in 10
- Common: affects 1 to 10 users in 100
- Uncommon: affects 1 to 10 users in 1,000
- Rare: affects 1 to 10 users in 10,000
- Very rare: affects less than 1 user in 10,000
- Not known: cannot be estimated from the available data

Very common:

- increase in appetite and weight gain
- drowsiness or sleepiness
- headache
- dry mouth

Common:

- lethargy
- dizziness
- shakiness or tremor
- 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)
- tiredness
- vivid dreams
- confusion
- feeling anxious
- sleeping problems

Uncommon:

- feeling elated or emotionally 'high' (mania)
→Stop taking Zispin SolTab and tell your doctor straight away.
- 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

Rare:

- yellow colouring of eyes or skin; this may suggest disturbance in liver function (jaundice)
→Stop taking Zispin SolTab and tell your doctor straight away.
- muscle twitching or contractions (myoclonus)

Not known:

- signs of infection such as sudden unexplainable high fever, sore throat and mouth ulcers (agranulocytosis)
→Stop taking Zispin SolTab and contact your doctor straight away for a blood test.

In rare cases Zispin SolTab can cause disturbances in the production of blood cells (bone marrow depression). Some people become less resistant to infection because Zispin SolTab can cause a temporary shortage of white blood cells (granulocytopenia). In rare cases Zispin SolTab can also cause a shortage of red and white blood cells, as well as blood

platelets (aplastic anemia), a shortage of blood platelets (thrombocytopenia) or an increase in the number of white blood cells (eosinophilia).

- epileptic attack (convulsions)
→Stop taking Zispin SolTab 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 and unconsciousness. In very rare cases these can be signs of serotonin syndrome.
→Stop taking Zispin SolTab 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 paraesthesia)
- swelling in the mouth (mouth oedema)
- hyponatraemia
- inappropriate anti-diuretic hormone secretion

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.

5. How To Store Zispin SolTab

Keep out of the reach and sight of children.

Do not use Zispin SolTab 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

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

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

6. Further Information

What Zispin SolTab contains

- The active substance is mirtazapine. Zispin SolTab 45 mg orodispersible tablets contain 45 mg mirtazapine per orodispersible tablet.
- The other ingredients are sugar spheres, hypromellose, povidone K30, magnesium stearate, basic butylated methacrylate copolymer, aspartame (E951), anhydrous citric acid, crospovidone (type A), mannitol (E421), microcrystalline cellulose, natural and artificial orange flavour (No. SNO27512) and sodium hydrogen carbonate.

What Zispin SolTab looks like and contents of the pack

Zispin SolTab are orodispersible tablets. Zispin SolTab 45 mg orodispersible tablets are round, white, standard bevelled-edge tablets coded with 'TZ/4' on one side. The orodispersible tablets are packed in a child-resistant perforated unit dose blister. For Zispin SolTab 45 mg orodispersible tablets the following pack sizes are available: 30 and 90 orodispersible tablets (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Organon Laboratories Ltd,
Cambridge Science Park,
Milton Road,
Cambridge, CB4 0FL
United Kingdom

Manufacturer

N.V. Organon,
Kloosterstraat 6, P.O. Box 20,
5340 BH Oss,
The Netherlands

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

Belgium	Remergon SolTab
Denmark	Remeron Smelt
France	Norset
Germany	Remergil SolTab
Iceland	Remeron Smelt
Ireland	Zispin SolTab
Luxembourg	Remergon SolTab
Spain	Rexer Flas
United Kingdom	Zispin SolTab

This leaflet was last revised/approved in September 2008.