

Package leaflet: Information for the user

Zalonil 10 mg orodispersible tablets

Zalonil 15 mg orodispersible tablets

Zalonil 30 mg orodispersible tablets

aripiprazole

Read all of this leaflet carefully before you start taking this medicine as 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 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 Zalonil orodispersible tablets is and what it is used for
2. What you need to know before you take Zalonil orodispersible tablets
3. How to take Zalonil orodispersible tablets
4. Possible side effects
5. How to store Zalonil orodispersible tablets
6. Contents of the pack and other information

1. What Zalonil is and what it is used for

Zalonil orodispersible tablets contains the active substance aripiprazole and belong to a group of medicines called antipsychotics. It is used in the treatment of adults and adolescents patients 15 years of age or older who suffer from a disease characterized by symptoms such as hearing, seeing or feeling things that are not there, mistrust, misjudgments, incoherent speech and behavior, and emotional apathy. People in this condition may also feel depressed, guilty, anxious or tense.

Zalonil orodispersible tablets is used in the treatment of adults and adolescents 13 years of age or older who suffer from a condition with symptoms such as feeling "euphoric," having excessive energy, needing to sleep much less than usual, talking very fast with very quick ideas and sometimes severe irritability. In adults patients who have responded to treatment with Zalonil orodispersible tablets it also prevents this condition from recurring.

2. What you need to know before you take Zalonil orodispersible tablets

Do not take Zalonil orodispersible tablets

- if you are allergic to aripiprazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking Zalonil orodispersible tablets.

Suicidal thoughts and behavior have been reported during treatment with aripiprazole. Tell your doctor immediately if you have any thought or feeling of harming yourself.

Aripiprazole can cause drowsiness, a drop in blood pressure on standing up, dizziness and changes in your ability to move and balance, which can lead to falls. You should be careful, particularly if you are elderly or have any weakness.

Before treatment with Zalonil orodispersible tablets, inform your doctor if you suffer from:

- high blood sugar levels (characterized by symptoms such as excessive thirst, passing large amounts of urine, increased appetite, and feeling weak) or a family history of diabetes;
- seizures (convulsions), as your doctor may want to carry out more careful monitoring;
- involuntary, irregular muscle movements, especially in the face;
- cardiovascular diseases, family history of cardiovascular diseases, stroke or "mini" stroke, abnormal blood pressure;
- blood clots, or a family history of blood clots, because antipsychotics have been associated with the formation of blood clots;
- past experience with excessive gambling habits.

If you are gaining weight, developing unusual movements, feeling drowsy that interferes with your normal daily activities, if you have difficulty swallowing or allergic symptoms, tell your doctor.

If you are an elderly patient who has dementia (loss of memory and other mental faculties), your doctor should be told by you or your healthcare provider/family member if you have had a stroke or a mild stroke.

Tell your doctor immediately if you have any thoughts or desires to harm yourself. Suicidal thoughts and behavior have been reported during treatment with aripiprazole.

Tell your doctor right away if you experience muscle stiffness or inflexibility with high fever, sweating, altered mental status, or a very fast or irregular heartbeat.

Tell your doctor if you, or your healthcare provider/family member, notice that you are developing a urge or desire to behave in ways that are unusual for you and that you cannot resist the urge, urge or temptation to do certain activities that could harm themselves or others. These are called impulse control disorders and can include behaviors such as addictive gambling, excessive food intake or excessive spending of money, abnormally high sex drive or worry, with increased sexual thoughts or feelings.

Your doctor may need to stop or adjust the dose.

Children and adolescents

Do not use this medicine in children and adolescents under the age of 13. It is not known whether it is safe and effective in these patients.

Other medicines and Zalonil orodispersible tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription.

Medicines to lower blood pressure: Zalonil orodispersible tablets may increase the effect of medicines used to lower blood pressure. Tell your doctor if you take medication to control blood pressure.

If you take Zalonil orodispersible tablets with some medicines it may mean that your doctor will need to change your dose of Zalonil orodispersible tablets or your other medicines. It is especially important to mention the following to your doctor:

- heart rhythm correction medicines (such as quinidine, amiodarone, flecainide);
- antidepressants or herbal medicines used to treat depression and anxiety (such as fluoxetine, paroxetine, venlafaxine, St. John's wort);
- antifungal medicines (such as ketoconazole, itraconazole);
- certain medicines to treat HIV infection (such as protease inhibitors, e.g., indinavir, ritonavir);
- anticonvulsants used to treat epilepsy (such as carbamazepine, phenytoin, phenobarbital);
- certain antibiotics used to treat tuberculosis (rifabutin, rifampicin).

These medicines may increase the risk of side effects or reduce the effect of Zalonil orodispersible tablets; if you experience any unusual symptoms when taking any of these medicines together with Zalonil orodispersible tablets, you should consult your doctor.

Medications that increase serotonin levels are typically used in conditions including depression, generalized anxiety disorder, obsessive compulsive disorder (OCD), and social phobia, as well as migraine and pain:

- triptans, tramadol, and tryptophan used in conditions including depression, generalized anxiety, obsessive compulsive disorder (OCD), and social phobia, as well as migraine and pain;
- SSRIs (such as paroxetine and fluoxetine) used in depression, OCD, panic and anxiety;
- other antidepressants (such as venlafaxine and tryptophan) used in major depression;
- tricyclics (such as clomipramine and amitriptyline) used in depression;
- St. John's wort (*Hypericum perforatum*) used as a herbal medicine for mild depression;
- analgesics (such as tramadol and pethidine) used to relieve pain;
- triptans (such as sumatriptan and zolmitriptan) used to treat migraine.

These medicines can increase the risk of side effects; if you experience any unusual symptoms when taking any of these medicines together with Zalonil orodispersible tablets, you should consult your doctor.

Zalonil orodispersible tablets with food, drinks and alcohol
This medicine can be taken without regard meals.
Alcohol intake should be avoided.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

In newborns whose mothers used Zalonil orodispersible tablets in the last trimester of pregnancy (last three months) the following symptoms may occur: tremor, muscle stiffness and/or weakness, drowsiness, restlessness, breathing problems and feeding difficulties. If your baby develops any of these symptoms you may need to contact your doctor.

If you are taking Zalonil orodispersible tablets, your doctor will discuss with you whether you should breast-feed, considering the benefit that the therapy will have for you and the benefit that breast-feeding will have for your baby. You should not do both. Talk to your doctor about the best way to feed your baby if you are being treated with this medicine.

Driving and using machines

Dizziness and vision problems may occur during treatment with this medicine (see section 4). This should be taken into consideration in cases where full alertness is required, e.g. when driving a vehicle or using machines.

Zalonil orodispersible tablets contains aspartame

Patients who cannot take phenylalanine should be aware that Zalonil orodispersible tablets contains aspartame, which is a source of phenylalanine. It can be harmful to people with phenylketonuria.

Zalonil orodispersible tablets contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Zalonil orodispersible tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Talk to your doctor or pharmacist if you have any questions.

The recommended dose for adults is 15 mg once a day. However, your doctor may prescribe a lower or higher dose, up to a maximum of 30 mg once a day.

Use in children and adolescents

This medicine can be started at a low dose in the form of an oral solution (liquid).

The dose can be gradually increased to the recommended dose for adolescents of 10 mg once daily. However, your doctor may prescribe a lower or higher dose, up to a maximum of 30 mg once a day.

Talk to your doctor or pharmacist if you have the impression that the effect of Zalonil orodispersible tablets is too strong or too weak.

Try to take your Zalonil orodispersible tablets at the same time every day. It is not important whether or not you take it with food.

Do not open the blister until it is time for administration.

To remove a tablet, open the package and pull the blister strip to expose the tablet.

Do not push the tablet through the tape as this could damage the tablet. Immediately after opening the blister, and with dry hands, remove the orodispersible tablet and place it whole on the tongue. Tablet breakdown occurs rapidly in saliva. The orodispersible tablet can be taken with or without liquids.

Alternatively, disperse the tablet in water and drink the resulting suspension.

Even if you feel better, do not change or stop your daily dose of Zalonil orodispersible tablets without first consulting your doctor.

If you take more Zalonil orodispersible tablets than you should

If you notice that you have taken more Zalonil orodispersible tablets than your doctor has recommended (or if someone else has taken any of your Zalonil orodispersible tablets), contact your doctor immediately. If you cannot contact your doctor, go to the nearest hospital and take the medicine package.

Patients who took an overdose of aripiprazole experienced the following symptoms:

- fast heartbeat, agitation/aggressiveness, problems with speech;
- unusual movements (especially of the face or tongue) and reduced level of consciousness.

Other symptoms may include:

- acute confusion, convulsions (epilepsy), coma, a combination of fever, rapid breathing, sweating;
- muscle stiffness and drowsiness or apathy, slower breathing, suffocation, high or low blood pressure, abnormal heart rhythms.

Contact your doctor or the hospital immediately if you experience any of the above symptoms.

If you forget to take Zalonil orodispersible tablets

If you miss a dose, take the missed dose as soon as you remember, but do not take two doses on the same day.

If you stop taking Zalonil orodispersible tablet

Do not stop your treatment just because you feel better. It is important that you continue treatment with Zalonil orodispersible tablets for as long as your doctor prescribes.

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.

Common side effects (may affect up to 1 in 10 people):

- diabetes mellitus;
- difficulty sleeping;
- feeling of anxiety;
- feeling restless and unable to sit still, difficulty sitting still;
- uncontrollable muscle twitching movements, spasms, or writhing, restless legs;
- tremors;
- headaches;
- tiredness;
- somnolence;
- stunning;
- blurred and blurred vision;
- defecating less often or with difficulty;

- indigestion;
- bad disposition;
- greater production of saliva than normal;
- vomiting;
- feeling tired.

Uncommon side effects (may affect up to 1 in 100 people):

- increased blood levels of the hormone prolactin;
- too much sugar in the blood;
- depression;
- altered or increased sexual interest;
- uncontrollable movements of the mouth, tongue and limbs (tardive dyskinesia);
- muscle disorder causing twisting movements (dystonia);
- double vision;
- fast heartbeat;
- drop in blood pressure when standing up, which causes dizziness, lightheadedness or fainting;
- hiccups;
- eye sensitivity to light.

The following side effects have been reported since the marketing of oral aripiprazole but the frequency of their occurrence is not known:

- low levels of white blood cells;
- low levels of platelets;
- allergic reaction (e.g. swelling of the mouth, tongue, face and throat, itching, hives);
- onset or worsening of diabetes, ketoacidosis (ketones in the blood and urine), or coma;
- high blood sugar levels;
- insufficient levels of sodium in the blood;
- loss of appetite (anorexia);
- weight loss;
- weight gain;
- suicidal thoughts, suicide attempt and suicide;
- feeling of aggression;
- agitation;
- nervousness;
- combination of fever, muscle stiffness, rapid breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate, fainting (neuroleptic malignant syndrome);
- convulsions;
- serotonergic syndrome (a reaction that can cause feelings of great happiness, drowsiness, incoordination, restlessness, feeling drunk, fever, sweating or muscle stiffness);
- speech alteration;
- sudden unexplained death;
- life-threatening irregular heartbeat;
- heart attack;
- slower heartbeat;
- blood clots in the veins, especially in the legs (symptoms include swelling, pain, and redness in the leg), which can travel through the blood vessels to the lungs

causing chest pain and difficulty breathing (if you notice any of these symptoms, seek medical advice immediate);

- high blood pressure;
- fainting;
- accidental inhalation of food with risk of pneumonia (lung infection);
- spasm (involuntary contraction) of the muscles around the voice box;
- inflammation of the pâncreas;
- difficulty swallowing;
- diarrhea;
- abdominal discomfort;
- stomach discomfort;
- liver failure;
- inflammation of the liver;
- yellowing of the skin and the whites of the eyes;
- reports of changes in liver function laboratory tests values;
- rash;
- sensitivity to light;
- baldness;
- excessive sweating;
- abnormal breakdown of muscle which can lead to kidney problems;
- muscle pain;
- stiffness;
- involuntary leakage of urine (incontinence);
- difficulty urinating;
- withdrawal symptoms in newborn babies in case of exposure during pregnancy;
- prolonged and/or painful erection;
- difficulty controlling body temperature or elevation of body temperature;
- chest pain
- swelling of the hands, ankles or feet;
- in blood tests: fluctuation of blood sugar, increase in glycosylated hemoglobin;
- inability to resist the urge, urge or temptation to undertake certain activities that could harm you or others, which may include:
 - strong impulse to gamble excessively, despite serious personal or family consequences;
 - altered or increased sexual interest and behaviors of significant concern to yourself or others, for example, an increased sex drive;
 - excessive or uncontrollable purchases and spending;
 - binge eating (eating large amounts of food in a short period of time) or compulsive eating (eating more food than usual and more than you need to satisfy your hunger),
 - a tendency to wander (walking without aimlessly),
 - fixation of the eyeballs in one position.

Tell your doctor if you experience any of these behaviors; he will assess ways to manage or reduce symptoms.

In elderly patients with dementia, more fatalities were reported during aripiprazole therapy. Additionally, cases of stroke or mild stroke have been reported.

Additional side effects in children and adolescents

Adolescents 13 years of age and older had side effects similar in frequency and type to those seen in adults, with the exception of drowsiness, uncontrollable muscle twitching or spasms, restlessness and tiredness which were very common (more

than 1 in 10 patients) and upper abdominal pain, dry mouth, increased heart rate, weight gain, increased appetite, muscle spasms, uncontrollable limb movements, and feeling dizzy, especially when getting up from a lying or sitting position, which were common (more than 1 in 100 patients).

Reporting of side effects

If you get any side effects, including possible side effects not listed in this leaflet, please talk to your doctor, pharmacist or nurse. You can also report side effects directly to INFARMED, I.P. using the contacts details below. By reporting side effects, you can help provide more information on the safety of this medicine.

INFARMED, I.P.

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Website: <http://www.infarmed.pt/web/infarmed/submissaoram>

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5. How to store Zalonil orodispersible tablets

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 blister and carton after VAL. The expiry date refers to the last day of the indicated 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 protect the environment.

6. Contents of the pack and other information

What Zalonil orodispersible tablets contains

The active substance is aripiprazole.

Each orodispersible tablet contains 10 mg of aripiprazole.

Each orodispersible tablet contains 15 mg of aripiprazole.

Each orodispersible tablet contains 30 mg of aripiprazole.

The other components are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, anhydrous colloidal silica, magnesium stearate, vanilla flavor and aspartame (E951).

Zalonil 10 mg and 30 mg orodispersible tablets also contains iron oxide red (E 172)

Zalonil 15 mg orodispersible tablets also contains iron oxide yellow (E 172)

What Zalonil orodispersible tablets looks like and contents of the pack

Zalonil 10 mg orodispersible tablets are round and pink with the marking "10" on one side.

Zalonil 15 mg orodispersible tablets are round and yellow with the marking "15" on one side.

Zalonil 30 mg orodispersible tablets are round and pink with the marking "30" on one side.

Zalonil orodispersible tablets are packaged in aluminum-aluminum blisters, in packs containing 14, 28 or 49 orodispersible tablets.

It is possible that not all presentations will be marketed.

Marketing Authorization Holder

Pygen Lda.

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