

Zolinda®

PACKAGE LEAFLET: INFORMATION FOR THE USER

ZOLINDA 5 mg tablets
ZOLINDA 10 mg tablets
ZOLINDA 15 mg tablets
Aripiprazole

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 ZOLINDA IS AND WHAT IT IS USED FOR
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1. WHAT ZOLINDA IS AND WHAT IT IS USED FOR

ZOLINDA is one of a group of medicines called antipsychotics. It is used to treat adults and adolescents 15 years and older who suffer from a disease characterized by symptoms such as hearing, seeing or sensing things which are not there, suspiciousness, mistaken beliefs, incoherent speech and behavior and emotional flatness. People with this condition may also feel depressed, guilty, anxious or tense.

ZOLINDA is used to treat adults who suffer from a condition with symptoms such as feeling "high", having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability. It also prevents this condition from returning in patients who have responded to the treatment with **ZOLINDA**.

2. BEFORE YOU TAKE ZOLINDA

Do not take ZOLINDA

- If you are allergic (hypersensitive) to aripiprazole or any of the other ingredients of **ZOLINDA** (listed in section 6).

Take special care with ZOLINDA

Before treatment with **ZOLINDA**, tell your doctor if you suffer from

- High blood sugar (characterized by symptoms such as excessive thirst, passing of large amounts of urine, increase in appetite, and feeling weak) or family history of diabetes

Seizure

- Involuntary, irregular muscle movements, especially in the face
- Cardiovascular diseases, family history of cardiovascular disease, stroke or "mini" stroke, abnormal blood pressure

- Blood clots, or family history of blood clots, as antipsychotics have been associated with formation of blood clots

- Past experience of excessive gambling

If you notice you are gaining weight, experience any difficulty in swallowing or allergic symptoms, please tell your doctor.

If you are an elderly patient suffering from dementia (loss of memory and other mental abilities), you or your carer/relative should tell your doctor if you have ever had a stroke or "mini" stroke.

Tell your doctor immediately if you are having any thoughts or feelings about hurting yourself. Suicidal thoughts and behaviors have been reported during aripiprazole treatment.

Tell your doctor immediately if you suffer from muscle stiffness or inflexibility with high fever, sweating, altered mental status, or very rapid or irregular heart beat.

Children and adolescents

ZOLINDA is not for use in children and adolescents under 13 years. Ask your doctor or pharmacist for advice before taking **ZOLINDA**.

Taking other medicines

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

Blood pressure-lowering medicines: **ZOLINDA** may increase the effect of medicines used to lower the blood pressure. Be sure to tell your doctor if you take a medicine to keep your blood pressure under control.

Taking **ZOLINDA** with some medicines may need to change your dose of **ZOLINDA**. It is especially important to mention the following to your doctor:

- Medicines to correct heart rhythm
- Antidepressants or herbal remedy used to treat depression and anxiety
- Antifungal agents
- Certain medicines to treat HIV infection
- Anticonvulsants used to treat epilepsy

Medicines that increase the level of serotonin: triptans, tramadol, tryptophan, SSRIs (such as paroxetine and fluoxetine), tricyclics (such as clomipramine, amitriptyline), pethidine, St John's Wort and venlafaxine. These medicines increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with **ZOLINDA** tablets, you should see your doctor.

Taking ZOLINDA with food and drink

ZOLINDA can be taken regardless of meals.

Alcohol should be avoided when taking **ZOLINDA**.

Pregnancy and breast-feeding

You should not take ZOLINDA if you are pregnant unless you have discussed this with your doctor. Be sure to tell your doctor immediately if you are pregnant, think you may be pregnant, or if you are planning to become pregnant.

The following symptoms may occur in newborn babies, of mothers that have used **ZOLINDA** in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Be sure to tell your doctor immediately if you are breast-feeding.

If you are taking **ZOLINDA**, you should not breast-feed.

Driving and using machines

Do not drive or use any tools or machines, until you know how **ZOLINDA** affects you.

Important information about some of the ingredients of ZOLINDA

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

3. HOW TO TAKE ZOLINDA

Always take **ZOLINDA** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose is **15 mg once a day**. However your doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day.

Children and adolescents:

ZOLINDA may be started at a low dose. The dose may be gradually increased to the usual dose for adolescents of 10 mg once a day. However, your doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day.

If you have the impression that the effect of **ZOLINDA** is too strong or too weak, talk to your doctor or pharmacist.

Try to take the ZOLINDA tablet at the same time each day. It does not matter whether you take it with or without food. Always take the tablet with water and swallow it whole.

Even if you feel better, do not alter or discontinue the daily dose of **ZOLINDA** without first consulting your doctor.

If you take more ZOLINDA than you should

If you realize you have taken more **ZOLINDA** tablets than your doctor has recommended (or if someone else has taken some of your **ZOLINDA** tablets), contact your doctor right away. If you cannot reach your doctor, go to the nearest hospital and take the pack with you.

If you forget to take ZOLINDA

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

If you stop taking ZOLINDA tablets

Do not stop your treatment just because you feel better. It is important that you carry on taking your **ZOLINDA** tablets for as long as your doctor has told you to. **If you have any further questions on the use of this product, ask your doctor or pharmacist.**

4. POSSIBLE SIDE EFFECTS

Like all medicines, **ZOLINDA** 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 anxious,
- feeling restless and unable to keep still, difficulty sitting still,
- uncontrollable twitching, jerking or writhing movements, restless legs,
- trembling,
- headache,
- tiredness,
- sleepiness,
- light-headedness,
- shaking and blurred vision,
- decreased number of or difficulty making bowel movements,
- indigestion,
- feeling sick,
- more saliva in mouth 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 mouth, tongue and limbs (tardive dyskinesia),
- muscle disorder causing twisting movements (dystonia),
- double vision,
- fastheart beat,
- a fall in blood pressure on standing up which causes dizziness, light-headedness or fainting,
- hiccups.

The following side effects have been reported since the marketing of oral aripiprazole but the frequency for them to occur is not known:

- low levels of white blood cells,
 - low levels of blood platelets,
 - allergic reaction (e.g. swelling in 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,
 - not enough sodium in the blood,
 - loss of appetite (anorexia),
 - weight loss,
 - weight gain,
 - thoughts of suicide, suicide attempt and suicide,
 - excessive gambling,
 - feeling aggressive,
 - agitation,
 - nervousness,
 - combination of fever, muscle stiffness, faster breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate, fainting (neuroleptic malignant syndrome),
 - seizure,
 - serotonin syndrome (a reaction which may cause feelings of great happiness, drowsiness, clumsiness, restlessness, feeling of being drunk, fever, sweating or rigid muscles),
 - speech disorder,
 - sudden unexplained death,
 - life-threatening irregular heart beat,
 - heart attack,
 - slowerheart beat,
 - blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing (if you notice any of these symptoms, seek medical advice immediately),
 - high blood pressure,
 - fainting,
 - accidental inhalation of food with risk of pneumonia (lung infection),
 - spasm of the muscles around the voice box,
 - inflammation of the pancreas,
 - difficulty swallowing,
 - diarrhoea,
 - abdominal discomfort,
 - stomach discomfort,
 - liver failure,
 - inflammation of the liver,
 - yellowing of the skin and white part of eyes,
 - reports of abnormal liver tests values,
 - skin rash,
 - sensitivity to light,
 - baldness,
 - excessive sweating,
 - abnormal muscle breakdown which can lead to kidney problems,
 - muscle pain,
 - stiffness,
 - involuntary loss of urine (incontinence),
 - difficulty in passing urine,
 - withdrawal symptoms in newborn babies in case of exposure during pregnancy,
 - prolonged and/or painful erection,
 - difficulty controlling core body temperature or overheating,
 - chest pain,
 - swelling of hands, ankles or feet,
 - in blood tests: fluctuating blood sugar, increased glycosylated haemoglobin.
- In elderly patients with dementia, more fatal cases have been reported while taking aripiprazole. In addition, cases of stroke or "mini" stroke have been reported.

Additional side effects in children and adolescents

Adolescents aged 13 years and older experienced side effects that were similar in frequency and type to those in adults except that sleepiness, uncontrollable twitching or jerking movements, restlessness, and tiredness were very common (greater than 1 in 10 patients) and upper abdominal pain, dry mouth, increased heart rate, weight gain, increased appetite, muscle twitching, uncontrolled movements of the limbs, and feeling dizzy, especially when getting up from a lying or sitting position, were common (greater than 1 in 100 patients).

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 The National Pharmacovigilance and Drug Safety Centre (NPC). By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZOLINDA

Do not store above 30°C

Keep out of the reach and sight of children.

Do not use **ZOLINDA** after the expiry date which is stated on the blister and on the carton.

Store in the original package in order to protect from 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 ZOLINDA contains

- The active substance is aripiprazole.

ZOLINDA 5 mg tablets: each tablet contains 5 mg of aripiprazole.

ZOLINDA 10 mg tablets: each tablet contains 10 mg of aripiprazole.

ZOLINDA 15 mg tablets: each tablet contains 15 mg of aripiprazole.

- The other ingredients are:

ZOLINDA 5 mg tablets:

Magnesium Stearate, Avicel PH 102 NF, Croscarmellose Sodium Type A NF, Spectracol Brilliant Blue LK, and Lactose NF Fast Flow.

ZOLINDA 10 mg tablets:

Magnesium Stearate, Avicel PH 102 NF, Croscarmellose Sodium Type A NF, Iron Oxide Red, and Lactose NF Fast Flow.

ZOLINDA 15 mg tablets:

Magnesium Stearate, Avicel PH 102 NF, Croscarmellose Sodium Type A NF, Iron Oxide Yellow, and Lactose NF Fast Flow.

What ZOLINDA looks like and contents of the pack

ZOLINDA 5 mg tablets are light blue, round, biconvex uncoated tablets, engraved with "32" on one side and plain on the other side.

ZOLINDA 10 mg tablets are a light pink, round, biconvex uncoated tablets, engraved with "33" on one side and plain on the other side.

ZOLINDA 15 mg tablets are a light yellow, round, biconvex uncoated tablets, engraved with "34" on one side and plain on the other side.

Each pack contains 30 tablets

Marketing Authorization Holder & Manufacturer

SPIMACO

Al-Qassim Pharmaceutical Plant
Saudi Arabia

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"Zolinda" is a trade mark
342L716

To report any side effect(s):

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2340.
- Reporting hotline: 19999
- E-mail: npc.drug@sfd.gov.sa
- Website: www.sfd.gov.sa/npc

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacists who sold the medicament.
- The doctor and the pharmacists are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists