

## **Package leaflet: Information for the user**

### **Aripiprazole 10 mg orodispersible tablets Aripiprazole 15 mg orodispersible tablets**

**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 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 Aripiprazole is and what it is used for
2. What you need to know before you take Aripiprazole
3. How to take Aripiprazole
4. Possible side effects
5. How to store Aripiprazole
6. Contents of the pack and other information

#### **1. What Aripiprazole is and what it is used for**

Aripiprazole contains the active substance aripiprazole and belongs to a group of medicines called antipsychotics.

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

Aripiprazole is used to treat adults and adolescents aged 13 years and older 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. In adults it also prevents this condition from returning in patients who have responded to the treatment with Aripiprazole.

#### **2. What you need to know before you take Aripiprazole**

##### **Do not take Aripiprazole**

- 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 Aripiprazole.

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

Before treatment with Aripiprazole, tell your doctor if you suffer from

- high blood sugar (characterised by symptoms such as excessive thirst, passing of large amounts of

- urine, increase in appetite, and feeling weak) or family history of diabetes
- seizures as your doctor may want to monitor you closely
- involuntary, irregular muscle movements, especially in the face
- cardiovascular diseases (diseases of the heart and circulation), 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, develop unusual movements, experience somnolence that interferes with normal daily activities, 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 behaviours 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 heartbeat.

Tell your doctor if you, your family or caregiver notice that you are developing impulses or anxieties to behave in an unusual way for you and that you cannot resist the urge, instinct or temptation to carry out certain activities that could harm you or others. This is called an impulse control disorder and may include behaviours such as gambling addiction, excessive intake or expenditure, abnormally high sex appetite or concern about an increase in sexual thoughts and feelings.

Your doctor may consider adjusting or interrupting the dose.

Aripiprazole may cause sleepiness, fall in blood pressure when standing up, dizziness and changes in your ability to move and balance, which may lead to falls. Caution should be taken, particularly if you are an elderly patient or have debility.

### **Children and adolescents**

Do not use this medicine in children and adolescents under 13 years of age. If you do not know whether it is safe and effective in these patients.

### **Other medicines and aripiprazole**

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

Blood pressure-lowering medicines: Aripiprazole 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 Aripiprazole with some medicines may mean the doctor will need to change your dose of Aripiprazole or the other medicines. It is especially important to mention the following to your doctor:

- medicines to correct heart rhythm (such as quinidine, amiodarone, flecainide)
- antidepressants or herbal remedy used to treat depression and anxiety (such as fluoxetine, paroxetine, venlafaxine, St. John's Wort)
- medicines to treat fungal infections (antifungal agents) (such as ketoconazole, itraconazole)
- certain medicines to treat HIV infection (such as efavirenz, nevirapine, a 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 Aripiprazole; if you get any unusual symptom taking any of these medicines together with Aripiprazole you should see your doctor.

Medicines that increase the level of serotonin are typically used in conditions including depression, generalised anxiety disorder, obsessive-compulsive disorder (OCD) and social phobia as well as migraine and pain:

- triptans, tramadol and tryptophan used for conditions including depression, generalised anxiety disorder, obsessive-compulsive disorder (OCD) and social phobia as well as migraine and pain
- selective-serotonin-reuptake-inhibitors (SSRIs) (such as paroxetine and fluoxetine) used for depression, OCD, panic and anxiety
- other anti-depressants (such as venlafaxine and tryptophan) used in serious depression
- tricyclic antidepressants (such as clomipramine and amitriptyline) used in depressive diseases
- St John's Wort (*Hypericum perforatum*) used as an herbal remedy for mild depression
- painkillers (such as tramadol and pethidine) used to relieve pain
- triptans (such as sumatriptan and zolmitriptan) used to treat migraine

These medicines may increase the risk of side effects; if you get any unusual symptom taking any of these medicines together with Aripiprazole, you should see your doctor.

#### **Aripiprazole with food, drink and alcohol**

This medicine can be taken regardless of meals.

Alcohol 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 or pharmacist for advice before using this medicine.

The following symptoms may occur in new-born babies, of mothers that have used Aripiprazole 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.

If you are taking Aripiprazole, your doctor will discuss with you whether you should breast-feed your child considering the treatment benefit for you and the breast-feeding benefit for your child. If you are taking Aripiprazole, you should not breast-feed. Talk to your doctor about the best way to feed your baby if you are taking this medicine.

#### **Driving and using machines**

During treatment with this medicine, dizziness and vision problems may occur during treatment with this medicine (see section 4).

This should be considered when maximum attention is required, for example, when driving or handling operating machinery.

#### **Aripiprazole contains sodium**

This medicinal product contains less than 23 mg of sodium (1 mmol) per tablet, which is why it is essentially considered 'sodium-free'.

### **3. How to take Aripiprazole**

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

**The recommended dose for adults is 15 mg once daily.** However your doctor may prescribe a lower and higher dose to a maximum of 30 mg once daily.

#### **Use in children and adolescents**

This medicinal product may be started at a low dose with the oral solution (liquid) form.

The dose may be gradually increased to **the recommended 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 daily.

If you consider that the action of Aripiprazole is too strong or weak, tell your doctor or pharmacist.

**Try to take the orodispersible tablet of Aripiprazole at the same time each day.** It does not matter whether you take it with or without food.

Do not open the blister until ready to administer. For single tablet removal, open the package and peel back the foil on the blister to expose the tablet. Do not push the tablet through the foil because this could damage the tablet. Immediately upon opening the blister, using dry hands, remove the tablet and place the entire orodispersible tablet on the tongue. Tablet disintegration occurs rapidly in saliva. The orodispersible tablet can be taken with or without liquid.

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

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

#### **If you take more Aripiprazole than you should**

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

Patients who have taken too much aripiprazole have experienced the following symptoms:

- rapid heartbeat, agitation/aggressiveness, speech disorders.
- unusual movements (especially of the face or tongue) and reduced consciousness.

Other symptoms may include:

- acute confusional state (epilepsy), coma, combination of fever, faster breathing, sweating,
- muscle stiffness, and drowsiness, slower breathing, drowning, high or low blood pressure, abnormal heart rhythms.

Contact your doctor or go to the nearest hospital if you experience any of these symptoms.

#### **If you forget to take Aripiprazole**

If you miss a dose, take the missed dose as soon as you remember but do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Aripiprazole**

Do not stop your treatment just because you feel better. It is important that you carry on taking your Aripiprazole tablets for as long as your doctor has told you to.

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 patients):**

- diabetes mellitus,
- difficulty sleeping,
- anxiety,
- feeling restless and unable to keep still, difficulty sitting still,
- akathisia (an uncomfortable feeling of inner restlessness and a compelling need to move constantly),
- uncontrollable twitching, jerking or writhing movements,
- trembling,
- headache,
- tiredness,
- sleepiness,
- dizziness,
- shaking and blurred vision,
- decreased number or difficulty making bowel movements (constipation),
- indigestion,
- nausea(feeling sick),
- more saliva in mouth than normal,
- vomiting,
- feeling tired.

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

- 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),
- restless legs,
- double vision,
- light sensitivity to eye,
- fast heartbeat,
- a fall in blood pressure on standing up which causes dizziness, light-headedness or fainting,
- hiccups.

**The following side effects have been reported during the marketing experience with oral aripiprazole though their frequency for has not been established:**

- low levels of white blood cells,
- low levels of blood platelets,
- allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching and 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,
- 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),

- seizures,
- 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,
- fixation of the eyeballs in one position,
- 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 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 (a part of the larynx),
- inflammation of the pancreas,
- difficulty swallowing,
- diarrhoea,
- abdominal discomfort,
- stomach discomfort,
- hepatic failure,
- liver inflammation,
- yellowing of the skin and white part of eyes,
- reports of abnormal liver tests values,
- skin rash,
- skin sensitivity to light,
- baldness,
- excessive sweating,
- serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia),
- abnormal muscle breakdown which can lead to kidney problems,
- muscle pain,
- stiffness,
- involuntary loss of urine (incontinence),
- difficulty in passing urine,
- withdrawal symptoms in new-born 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 levels, increased glycosylated haemoglobin.
- inability to resist the urge, instinct or temptation to perform an action that may be harmful to you or others, including:
  - strong urge to gamble excessively despite serious personal or family consequences
  - altered or increased sexual interest and worrying behaviour for you or others, for example, increased sexual appetite
  - uncontrollable excessive purchasing

- binge eating (intake of large amounts of food in a short period of time) or compulsive intake (intake of more food than normal and more than necessary to satisfy hunger)
- tendency to wander away

Tell your doctor if you experience any of these behaviours; your doctor will discuss explain how to manage or reduce these symptoms.

A greater incidence of fatalities has been recorded in elderly patients with dementia, while receiving 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 (up to 1 in 10 patients).

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for 'MHRA Yellow Card' in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Aripiprazole**

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 on the container after EXP. The expiry date refers to the last day of that month. Store in the original package in order to protect from moisture.

Do not throw away any medicines via wastewater or household waste. If you are not sure, ask your pharmacist how to throw away medicines and packages you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Aripiprazole 10 mg orodispersible tablets contain**

- The active substance is aripiprazole. Each orodispersible tablet contains 10 mg of aripiprazole.
- The other ingredients are mannitol/maize starch, tartaric acid (E-334), microcrystalline cellulose, sodium potato starch glycolate, tutti frutti essence, red iron oxide (E-172), sodium saccharin (E-954), colloidal anhydrous silica, magnesium stearate.

#### **What Aripiprazole 15 mg orodispersible tablets contain**

- The active substance is aripiprazole. Each orodispersible tablet contains 15 mg of aripiprazole.
- The other ingredients are mannitol/maize starch, tartaric acid (E-334), microcrystalline cellulose, sodium potato starch glycolate, tutti frutti essence, yellow iron oxide (E-172), sodium saccharin (E-954), colloidal anhydrous silica, magnesium stearate.

### **What Aripiprazole looks like and contents of the pack**

Aripiprazole 10 mg is supplied as pink, round, flat and debossed with A10 on one side orodispersible tablets. Aripiprazole 10 mg orodispersible tablets are available as packs of 14, 28 and 49.

Aripiprazole 15 mg is supplied as yellow, round, biconvex and debossed with A15 on one side orodispersible tablets. Aripiprazole 15 mg orodispersible tablets are available as packs of 14, 28 and 49.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Neon Healthcare Ltd.

8 The Chase, John Tate Road, Hertford, SG13 7NN, UK

### **Manufacturer**

LABORATORIOS NORMON, S.A.

Ronda de Valdecarrizo, 6, 28760 Tres Cantos, Madrid, Spain

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