Package leaflet: Information for the user
Lemilvo 10 mg orodispersible tablets
Lemilvo 15 mg orodispersible tablets
Lemilvo 30 mg orodispersible tablets

aripiprazole

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 Lemilvo is and what it is used for

Lemilvo 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.

Lemilvo / 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 Lemilvo.

2. What you need to know before you take Lemilvo

Do not take Lemilvo:
- 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 Lemilvo 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
- 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, 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 heart beat.

Children and adolescents
Lemilvo is not for use in children and adolescents under 13 years of age. Ask your doctor or pharmacist for advice before taking Lemilvo. It is not known if it is safe.

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

Blood pressure-lowering medicines: Lemilvo 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 Lemilvo with some medicines may need to change your dose of Lemilvo. 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 Lemilvo, you should see your doctor.

Lemilvo with food, drink and alcohol
Lemilvo 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 for advice before taking this medicine.
The following symptoms may occur in newborn babies, of mothers that have used Lemilvo 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 Lemilvo, you should not breast-feed.

Driving and using machines
Do not drive or use any tools or machines, until you know how Lemilvo affects you.

Lemilvo contains aspartame
Patients who cannot take phenylalanine should note that Lemilvo orodispersible tablets contain aspartame, which is a source of phenylalanine. May be harmful for people with phenylketonuria.

3. How to take Lemilvo

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 a day. However your doctor may prescribe a lower or higher dose to a maximum of 30 mg once a day.

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 a day.

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

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

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 Lemilvo without first consulting your doctor.

If you take more Lemilvo than you should
If you realise you have taken more Lemilvo orodispersible tablets than your doctor has recommended (or if someone else has taken some of your Lemilvo orodispersible 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 Lemilvo
If you miss a dose, take the missed dose as soon as you remember. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Lemilvo
Do not stop your treatment just because you feel better. It is important that you carry on taking your Lemilvo 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 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,
- fast heart 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,
- slower heart 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA 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 Lemilvo

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 carton.

Do not store above 25°C.
Store in the original package in order to protect from moisture.

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 Lemilvo contains

- The active substance is aripiprazole Each orodispersible contains 10mg, 15mg, 30mg of aripiprazole.
- The other ingredients are: Microcrystalline cellulose, Colloidal anhydrous silica Aspartame (E951), Vanilla flavour (Maize maltodextrin, Flavouring substances, Propylene glycol (E1520)), Magnesium stearate, Croscarmellose sodium (E468) and Yellow iron oxide (E172) for 15mg and 30mg orodispersible.

What Lemilvo looks like and contents of the pack

Orodispersible tablet 10 mg
Round and white, 7 mm with "1" debossed on one side and "ZT" on the other.

Orodispersible tablet 15 mg
Round and yellow mottled, 8 mm with "2" debossed on one side and "ZT" on the other.

Orodispersible tablet 30 mg
Round and yellow mottled, 10.5 mm with "4" debossed on one side and "ZT" on the other.

Pack sizes:
Blister (OPA/Aluminium/PVC/Aluminium):

Push-through blisters packed in cartons containing 14, 28, 30, 56, or 98 orodispersible tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Actavis Group PTC ehf.
Reykjavikurvegi 76-78
220 Hafnarfjordur
Iceland

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

Denmark	Lemilvo
Bulgaria	Lemilvo
Cyprus	Lemilvo

Greece	Lemilvo 10mg διασπειρόμενα στο στόμα δισκία Lemilvo 15mg διασπειρόμενα στο στόμα δισκία
Estonia	Lemilvo
Hungary	Lemilvo 10 mg, 15 mg, 30 mg szájban diszpergálódó tabletta
Ireland	Lemilvo 10 mg Orodispersible Tablets Lemilvo 15 mg Orodispersible Tablets Lemilvo 30 mg Orodispersible Tablets
Malta	Lemilvo
Lithuania	Lemilvo 10 mg burnoje dispeguojamosios tabletės Lemilvo 15 mg burnoje dispeguojamosios tabletės
Latvia	Lemilvo 10 mg mutē disperģējamās tabletesLemilvo 15 mg mutē disperģējamās tabletes
Poland	Lemilvo
Romania	Lemilvo 10 mg, 15 mg comprimate orodispersabile
Slovakia	Lemilvo 10 mg Lemilvo 15 mg
Slovenia	Lemilvo 10 mg, 15 mg orodisperzibilne tablete

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