



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 XALIPRO® is and what it is used for
2. Before you take XALIPRO®
3. How to take XALIPRO®
4. Possible side effects
5. How to store XALIPRO®
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1. WHAT XALIPRO® IS AND WHAT IT IS USED FOR

XALIPRO® is one of a group of medicines called antipsychotics.

It is used to treat adults and adolescents aged 15 years and older who suffer from a disease called schizophrenia 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.

XALIPRO® is used to treat adults and adolescents aged 13 years and older who suffer from a condition called mania 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 XALIPRO®.

2. BEFORE YOU TAKE XALIPRO®
Do not take XALIPRO®

If you are allergic (hypersensitive) to aripiprazole or any of the other ingredients of XALIPRO® (see section 6).

Take special care with XALIPRO®

Before treatment with XALIPRO®, 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, 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 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

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

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: XALIPRO® 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 XALIPRO® with some medicines may need to change your dose of XALIPRO®. 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

Taking XALIPRO® with food and drink

XALIPRO® can be taken regardless of meals. Alcohol should be avoided when taking XALIPRO®,

Pregnancy and breast-feeding

You should not take XALIPRO® 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 XALIPRO® 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 XALIPRO®, you should not breast-feed.

Driving and using machines

Do not drive or use any tools or machines, until you know how XALIPRO® affects you.

Important information about some of the ingredients of XALIPRO®

XALIPRO® contains lactose (a type of sugar). 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 XALIPRO®

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

Adults:

• The usual 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:

• XALIPRO® 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 XALIPRO® is too strong or too weak, talk to your doctor or pharmacist.

Try to take the XALIPRO® 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 XALIPRO® without first consulting your doctor.

If you take more XALIPRO® than you should

If you realize you have taken more XALIPRO® than your doctor has recommended (or if someone else has taken some of your XALIPRO®), 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 XALIPRO®

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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, XALIPRO® can cause side effects, although not everybody gets them. The frequency of possible side effects listed below is defined using the following convention:

- 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: frequency cannot be estimated from the available data

Common side effects: uncontrollable twitching or jerking movements, headache, tiredness, nausea, vomiting, an uncomfortable feeling in the stomach, constipation, increased production of saliva, light-headedness, trouble sleeping, restlessness, feeling anxious, sleepiness, shaking and blurred vision.

Uncommon side effects: some people may feel dizzy, especially when getting up from a lying or sitting position, or may experience a fast heart rate.

Some people may feel depressed.

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

Changes in the levels of some blood cells; unusual heart beat, sudden unexplained death, heart attack; allergic reaction (e.g. swelling in the mouth, tongue, face and throat, itching, rash); high blood sugar, onset or worsening of diabetes, ketoacidosis (ketones in the blood and urine) or coma, low sodium level in the blood; weight gain, weight loss, anorexia; nervousness, agitation, feeling anxious, excessive gambling; thoughts of suicide, suicide attempt and suicide; speech disorder, seizure, combination of fever, muscle stiffness, faster breathing, sweating, reduced consciousness and sudden changes in blood pressure and heart rate; fainting, high blood pressure, 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); spasm of the muscles around the voice box, accidental inhalation of food with risk of pneumonia, difficulty in swallowing; inflammation of the pancreas; inflammation of the liver, yellowing of the skin and white part of eyes, reports of abnormal liver test values, abdominal and stomach discomfort, diarrhoea; skin rash and sensitivity to light, unusual hair loss or thinning, excessive sweating; stiffness or cramps, muscle pain, weakness; involuntary loss of urine, difficulty in passing urine; prolonged and/or painful erection; difficulty controlling core body temperature or overheating, chest pain, and swelling of hands, ankles or feet.

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).

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.

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 XALIPRO®

Keep out of reach and sight of children.

Do not use XALIPRO® after the expiry date which is stated on the blister and on the carton. Do not store above 30°C.

Store in the original package.

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 XALIPRO® contains

The active substance is aripiprazole.

XALIPRO® 10 mg: Each tablet contains 10 mg aripiprazole.

XALIPRO® 15 mg: Each tablet contains 15 mg aripiprazole.

Excipients: Lactose monohydrate, microcrystalline cellulose, corn starch, low-substituted hydroxypropyl cellulose, magnesium stearate,

XALIPRO® 10 mg contains red ferric oxide and XALIPRO® 15 mg contains yellow ferric oxide

What XALIPRO® looks like and contents of the pack

XALIPRO® 10 mg
Pink, modified rectangle shaped, uncoated tablets debossed with 'CL 74' on one side and plain on the other side.

XALIPRO® 15 mg
Yellow, round shaped, uncoated tablets debossed with 'CL 75' on one side and plain on the other side.

XALIPRO® 10 and 15 mg are available in blister packs of 30 tablets.

For more information about this medicinal product, please contact:

Algorithm SAL
Tel: +961-9-222050

To report any side effect:

Lebanon and all MENA countries
Algorithm SAL
Fax: +961-9-222141
Email: pharmacovigilance@algx.net
Website: www.algorithm-lb.com

Also contact the relevant competent authority.

This is a Medicament

- 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 pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their 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.

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