



Please read the package leaflet that comes with your medicine for further information.

Reference

1. *Aripiprazole Sandoz, Summary of Product Characteristics*

Suspected adverse reactions and medication errors should be reported to
Medical Logistics Ltd
No 8, Ivo Muscat Azzopardi Street, St. Julian's STJ 1905 - Malta
T: +356 2755 9990
E: safety@medicallogisticsltd.com

Additionally, report forms can be downloaded from
www.medicinesauthority.gov.mt/adrportal
and sent by post or email to
ADR reporting
203, level 3 Rue D'Argens, Gzira GZR 1368 - Malta
E: postlicensing.medicinesauthority@gov.mt



SANDOZ
a Novartis company

Aripiprazole Sandoz



**Information Brochure for
Patients and Caregivers**

This information brochure contains important safety information that you need to be aware of before and during treatment with Aripiprazole Sandoz.

This information is intended to supplement, not substitute for, the expertise and judgment of your physician, pharmacist or other healthcare professional.

Consult your healthcare professional before using this drug and do not attempt to self-treat any symptoms without consulting him or her during the therapy.

What is Aripiprazole Sandoz and who should take it?

Aripiprazole Sandoz is indicated for the treatment of moderate to severe manic episodes in Bipolar I Disorder which can involve a "high" feeling, having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability. For this disease, Aripiprazole Sandoz is indicated in adults and adolescents aged 13 years and older. **Patients who are younger than 13 years old should not take this medicine to treat manic episodes. The indicated age range is 13-17 years.**

In adults it also prevents this condition from returning in patients who have responded to the treatment with Aripiprazole Sandoz.

What can you do to prevent the mentioned side effects or related complications?

It is important to try to prevent these effects or related complications. In order to reduce the risk of these side effects, there are some precautions you should take:

Inform your health care professional of all medical conditions before starting treatment with Aripiprazole Sandoz.

Caution is advised when using this drug in the elderly because they may be more sensitive to its side effects.

There is a greater potential for occurrence of adverse events with doses higher than 10 mg/day.

Which side effects of special concern can be caused by Aripiprazole Sandoz?

Aripiprazole Sandoz can cause adverse effects especially with doses higher than 10 mg/day, in particular:

- ▲ **Weight gain** is commonly seen in schizophrenic and bipolar mania patients due to other diseases they suffer from in parallel, other antipsychotics known to cause weight gain they often use in addition to Aripiprazole, and a poorly managed life-style. Weight gain has been reported among patients prescribed Aripiprazole Sandoz. Important risk factors for weight gain were diabetes, thyroid disorders and tumors of the pituitary gland. Weight gain might lead to severe complications.
- ▲ **Dose-related involuntary, irregular movements of face, tongue, or other parts of the body** have been reported. These symptoms can temporally deteriorate or can even arise after discontinuation of the Aripiprazole Sandoz treatment. They can be disfiguring and embarrassing for you. You may feel unable to remain calm, have disturbed sleep patterns, have impaired concentration or feel anxious. The condition is unlikely but it can be a serious side effect.

- ▲ **Sleepiness / Tiredness**

This drug may make you tired and sleepy. This occurs more frequently in adolescents aged 13 years and older than in adults. Sleepiness and tiredness were observed more frequently in children with bipolar disorder compared with children with schizophrenia.

If you notice you are gaining weight, develop unusual movements and/or experience somnolence that interferes with normal daily activities and/or if any of these effects persist or worsen, please tell your doctor.

Weight gain

Before using this medication, tell your doctor or pharmacist if you have a medical history of obesity. Weight control should be performed periodically to monitor your weight. Your doctor would consider if a dose reduction for Aripiprazole Sandoz would be necessary.

Restless, repetitive, or involuntary movements and rapid speech

You should be closely clinically monitored for these symptoms. Tell your doctor immediately if uncontrolled muscle movements (especially of the face or tongue) occur. Your doctor would consider if a dose reduction for Aripiprazole Sandoz would be necessary.

Sleepiness / Tiredness

Use caution engaging in activities requiring alertness such as driving or using machinery. Avoid alcoholic beverages.