



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
Health Care Professionals
Treating Adolescents with Bipolar Mania**

What should this brochure be used for?

This brochure is designed to help you prescribe Aripiprazole Sandoz appropriately for patients with moderate to severe manic episodes in Bipolar I Disorder and give appropriate instructions. It is only meant to be used as a guide. Please consult the Summary of Product Characteristics before prescribing Aripiprazole Sandoz.

Is Aripiprazole Sandoz indicated for the treatment of Bipolar I Disorder?

Aripiprazole Sandoz is approved for moderate to severe manic episodes in Bipolar I Disorder. The approved use of Aripiprazole Sandoz applies to different age groups:

- ▲ Treatment of moderate to severe manic episodes in Bipolar I Disorder and for the prevention of a new manic episode in adults who experienced predominantly manic episodes and whose manic episodes responded to Aripiprazole treatment.
- ▲ Treatment of moderate to severe manic episodes in Bipolar I Disorder up to 12 weeks in adolescents aged 13 years and older.

Due to safety concerns, what age group can use Aripiprazole Sandoz?

Do not prescribe Aripiprazole Sandoz to patients who are younger than 13 years old for the treatment of manic episodes. The indicated age range is 13-17 years.



Is it advisable to exceed the recommended dose of 10 mg/day of Aripiprazole Sandoz? What are the potential consequences regarding adverse effects?

There is greater potential for occurrence of adverse events with doses higher than 10 mg/day, in particular

- ▲ **Weight gain** is commonly seen in bipolar mania patients due to concomitant diseases, concomitantly taken antipsychotics known to cause weight gain, and a poorly managed life-style. Weight gain has been observed in post-marketing reports among patients prescribed Aripiprazole. Significant risk factors for weight gain were a history of diabetes, a thyroid disorder and a pituitary adenoma. It can result in significant health consequences. Please clarify a possible medical history of obesity with the patient before prescribing Aripiprazole Sandoz. Explain the importance to report weight gain, especially if it interferes with the patient's normal daily activities and/or if it persists or worsens. Monitor the patient's weight regularly. If clinically significant weight gain appears in a patient taking Aripiprazole Sandoz, there is a need for close monitoring and dosage adjustment. If necessary, consider a dose reduction of Aripiprazole Sandoz.
- ▲ **Dose-related extrapyramidal symptoms including akathisia, parkinsonism and tardive dyskinesia** can occur with Aripiprazole Sandoz. Respective symptoms can temporally deteriorate or even arise after discontinuation of the Aripiprazole Sandoz treatment. Explain possible symptoms to your patient and the importance to report every symptom to you immediately. Monitor the patient closely clinically for symptoms of extrapyramidal symptoms including tardive dyskinesia. If signs and symptoms of movement disorders appear in a patient taking Aripiprazole Sandoz, there is a need for further close monitoring and dosage adjustment. If necessary, consider a dose reduction of Aripiprazole Sandoz.
- ▲ **Somnolence / Fatigue** occurs more frequently in adolescents aged 13 years and older than in adults. In the paediatric population, somnolence and fatigue were observed more frequently in patients with bipolar disorder compared with patients with schizophrenia. Explain the possibility of somnolence and fatigue during the use of Aripiprazole Sandoz to your patient. Explain the importance to report somnolence or fatigue, especially if it interferes with the patient's normal daily activities and/or if it persists or worsens. Furthermore, instruct your patient on being cautioned about operating hazardous machines, including motor vehicles, until they are reasonably certain that Aripiprazole Sandoz does not affect them adversely. Alcoholic beverages should be avoided during therapy with Aripiprazole Sandoz.

Caution is advised when Aripiprazole Sandoz is used by elderly patients because they may be more sensitive to its undesirable effects.

Kindly remember to educate patients/caregivers and distribute the Patient/Caregiver Information Brochure.