

**Product Name:** RIPAZOL Disintegrating Tablet 30 mg

**Active Substances:** Aripiprazole

**Form:** 28 Oral disintegrating tablets

**Therapeutic indications:** "Ripazol is indicated for the treatment of schizophrenia (treatment of acute schizophrenia episodes and maintenance of clinical improvement during maintenance treatment) in adults and adolescents (13-17 years of age).

RIPAZOL is indicated in adults for the treatment of acute manic episodes associated with Bipolar I Disorder and for the prevention of recurrence and stabilization in bipolar I patients whose last episode is manic or mixed."

**Posology and method of administration:** "In adults

In schizophrenia

The recommended starting dose of RIPAZOL is 10 or 15 mg / day given once a day, regardless of the time of meals. The maintenance dose of RIPAZOL is 15 mg per day. In clinical studies, RIPAZOL has been shown to be effective at a dosage range of 10-30 mg / day. The maximum daily dose should not exceed 30 mg.

Bipolar Mania

RIPAZOL should be given as a single daily dose, regardless of the time of meals, the starting dose is usually 15 or 30 mg per day. If necessary, dose adjustment should not be made in less than 24 hours. Its antimanic efficacy (3-12 weeks) has been demonstrated in clinical studies for a dose range of 15-30 mg / day. The safety of doses above 30 mg / day has not been evaluated by clinical studies.

Prevention of new manic episodes in Bipolar I Disorder

To prevent recurrence of manic episodes in patients using aripiprazole, treatment should be continued at the same dose. In daily

dose adjustments, including dose reduction, the clinical situation should be taken into account.

#### Major depressive episodes

The recommended starting dose of RIPAZOL as an additional treatment to antidepressants is 5 mg / day as a single dose per day, regardless of the time of meals. Serum is effective at doses of 5 to 15 mg / day when administered in combination with antidepressants. Daily dose adjustment should be made in steps of at least 1 week. The maximum daily dose should not exceed 15 mg. Due to tolerability, the dose can be reduced to 2 mg when necessary.

Regular monitoring of the patient is required in the ongoing treatment with the addition of aripiprazole.

#### Pediatric population

##### Schizophrenia in adolescents (13-17 years old)

The recommended dose is 10 mg / day as a single daily dose regardless of the time of meals. The treatment should be started with a 2 mg dose in the first 2 days and the recommended daily dose should be reached to 10 mg by titrating to 5mg for the next 2 days. When appropriate, consecutive dose increases should be administered with doses of 5 mg, with a maximum daily dose not exceeding 30 mg. RIPAZOL is effective in a dosage range of 10-30 mg / day. Its effectiveness at doses exceeding 10 mg per day has not been studied in adolescents, but some patients may benefit from higher doses.

##### Irritability Associated with Autistic Disorder - Pediatric Patients (6-17 years)

The recommended target dose of RIPAZOL is 5 to 10 mg / day administered once a day and the maximum dose is 15 mg once a day. The dosage of RIPAZOL should be adjusted individually in accordance with tolerability and response.

Treatment should begin with 2 mg / day. Later, the dose should be increased to 5 mg / day, then increased to 10 mg / day or, if necessary,

to 15 mg / day. Dose adjustments up to 5 mg / day should be made gradually, intervals should be at least 1 week."