Zukaria™

Asenapine Maleate Sublingual Tablet

Presentation
Zukaria™ 5: Each sublingual tablet contains Asenapine Maleate INN equivalent to Asenapine 5 mg.

Description
Asenapine Maleate is an atypical antipsychotic that is available for sublingual administration. Asenapine belongs to the class dibenzo-oxepino pyrroles. It is a centrally active dopamine Type 2 (D2) antagonist and with predominant serotonin Type 2 (5-HT2A) antagonist activity.

Indications and usage
Asenapine is indicated for-
- Schizophrenia in adults
- Bipolar I disorder
  - Acute monotherapy for manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age
  - Adjunctive treatment to lithium or valproate in adults
  - Maintenance monotherapy treatment in adults

Dosage and administration

Indication	Initial dose	Recommended dose	Maximum dose
Schizophrenia-adults	5 mg sublingually twice daily	5 mg sublingually twice daily	10 mg sublingually twice daily
Schizophrenia-Maintenance treatment in adults	5 mg sublingually twice daily	5-10 mg sublingually twice daily	10 mg sublingually twice daily
Bipolar mania-adults: acute and maintenance monotherapy	5-10 mg sublingually twice daily	5-10 mg sublingually twice daily	10 mg sublingually twice daily
Bipolar mania-pediatric patients (10-17 years): monotherapy	2.5 mg sublingually twice daily	2.5-10 mg sublingually twice daily	10 mg sublingually twice daily
Bipolar mania-adults: as an adjunct to lithium or valproate	5 mg sublingually twice daily	5-10 mg sublingually twice daily	10 mg sublingually twice daily

• Sublingual tablets should not be swallowed. It should be placed under the tongue and left to dissolve completely. It will dissolve in saliva within seconds. Eating and drinking should be avoided for 10 minutes after administration.

Adverse reactions
The most common adverse reactions of Asenapine are akathisia, somnolence, oral hypoesthesia, dizziness, extrapyramidal symptoms, nausea, increased appetite, fatigue, increased weight.

Contraindications
Asenapine is contraindicated in patients with severe hepatic impairment and in patients with a known hypersensitivity to Asenapine.

Precautions
Caution should be exercised when asenapine is prescribed in elderly patients with dementia-related psychosis, QT prolongation, neuroleptic malignant syndrome, tardive dyskinesia, metabolic changes, orthostatic hypotension, leukopenia, neutropenia, agranulocytosis, seizures, potential for cognitive & motor impairment.

Drug interactions
Asenapine should be used with caution in combination with:
- Antihypertensive as it may cause hypotension
- Paroxetine (CYP2D6 substrate and inhibitor)

Use in pregnancy and lactation
Pregnancy: May cause extrapyramidal and/or withdrawal symptoms in neonates with third trimester exposure.
Lactation: Lactation studies have not been conducted to assess the presence of asenapine in human milk, the effects of asenapine on the breastfed infant, or the effects of asenapine on milk production.

Pediatric use
Safety and efficacy in the treatment of bipolar I disorder in patients less than 10 years of age, and patients with schizophrenia ages less than 12 years have not been evaluated.

Overdose
There is no specific antidote to Asenapine. Management of overdose should concentrate on supportive therapy, maintaining an adequate airway, oxygenation and ventilation, and management of symptoms. In case of severe extrapyramidal symptoms, anticholinergic medication should be administered. Close medical supervision and monitoring should continue until the patient recovers.

Storage
Do not store above 30°C. Keep away from light and out of the reach of children.

Commercial Pack
Zukaria™ 5: Each box contains 3 blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
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