

## FIRST TIME GENERIC APPROVAL

<b>Brand Name</b>	Saphris®
<b>Generic Name</b>	asenapine maleate
<b>Drug Manufacturer</b>	Sigmapharm Labs LLC

### New Drug Approval

#### TYPE OF CLINICAL UPDATE

First time generic

#### FDA APPROVAL DATE

December 10, 2020

#### LAUNCH DATE

N/A

#### REVIEW DESIGNATION

Standard

#### TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 206107

#### DISPENSING RESTRICTIONS

N/A

### Overview

#### INDICATION FOR USE

Asenapine sublingual tablets are an atypical antipsychotic indicated for:

- Schizophrenia in adults
- Bipolar I disorder
  - Acute monotherapy treatment of 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

#### MECHANISMS OF ACTION

The mechanism of action of asenapine in schizophrenia and bipolar I disorder is unknown. It has been suggested that the efficacy of asenapine in schizophrenia could be mediated through a combination of antagonist activity at D2 and 5-HT2A receptors

#### DOSE FORM AND STRENGTH

Sublingual tablets: 2.5 mg, 5 mg, 10 mg

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### DOSE & ADMINISTRATION

	<b>Starting Dose</b>	<b>Recommended Dose</b>	<b>Maximum Dose</b>
Schizophrenia – acute treatment in 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 to 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

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