



Saphris® (asenapine) – Expanded Indication

- On January 13, 2017, the FDA approved Allergan's [Saphris \(asenapine\)](#) for maintenance monotherapy treatment of bipolar I disorder in adults.
- Saphris is also FDA approved for:
 - Acute monotherapy of manic or mixed episodes, in adults and pediatric patients 10 to 17 years of age with bipolar I disorder
 - Adjunctive treatment to [lithium](#) or valproate [eg, [Depakote® \(divalproex\)](#)] in adults with bipolar I disorder
 - Schizophrenia in adults
- Efficacy of Saphris for the maintenance monotherapy treatment of bipolar I disorder was demonstrated in a clinical study of 252 patients randomized to treatment with Saphris or placebo for a period of 12 to 16 weeks. All patients were initially administered 5 or 10 mg twice daily, and the option to titrate down to 5 mg twice daily was provided based on tolerability.
 - Saphris was statistically superior to placebo in time to relapse as measured by bipolar disorder symptoms; requirement or initiation of an antipsychotic, antidepressant, or mood-stabilizing agent; requirement or initiation of psychiatric hospitalization; and investigator judgment to discontinue the study due to a mood event.
- The Saphris drug label was also updated with a dosing recommendation for bipolar I maintenance monotherapy.
 - Patients should continue on the Saphris dose that the patient received during stabilization (5 mg - 10 mg twice daily). Depending on the clinical response and tolerability in the individual patient, a dose of 10 mg twice daily can be decreased to 5 mg twice daily.
 - Refer to the Saphris drug label for the recommended doses for all other indications.
- Saphris carries a boxed warning regarding increased mortality in elderly patients with dementia-related psychosis.



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