

Clinical Summary:

Secuado (asenapine) Transdermal system 3.8 mg/24 hours, 5.7 mg/24 hours, 7.6 mg/24 hours

Background

- Schizophrenia is a severe, chronic psychiatric disorder that affects more than 21 million people worldwide. It has been estimated that 1.5% to 3.0% of total U.S. national healthcare expenditures are directed towards this patient population.
- Schizophrenia has a profound impact on affected individuals, their families, and society. Patients experience multiple limitations to independent living, healthy social relationships, and successful employment, and most require caregiver support.
- Many patients with schizophrenia also suffer from other comorbid psychiatric conditions, such as major depression, drug and alcohol abuse or dependency, and anxiety disorder.
- Adult patients with schizophrenia also have a dramatically increased risk of premature mortality, commonly caused by cardiovascular disease, cancer, and accidents.
- Patients with schizophrenia are also at an increased risk of suicide.
- Adherence to antipsychotic medication use is consistently low in patients with schizophrenia.
- Pivotal drivers of patient non-adherence are the side effects and clinical limitations of existing drugs.
- Based on the limitations of existing treatments, and the high cost burden of schizophrenia, a recent critical appraisal concluded that different modes of antipsychotic medication administration are needed.
- The development of a transdermal antipsychotic option helps to address the need for different modes of administration and offers schizophrenia patients a route of administration that may contribute to improved adherence.

Secuado Safety and Efficacy

- Secuado® (asenapine) transdermal (patch) system (HP-3070) is a U.S. Food and Drug Administration (FDA)-approved atypical antipsychotic that differs from the originally approved formulation of asenapine (sublingual [SL] asenapine; Saphris®) in dosage form and approved indications. Secuado is indicated for the treatment of adults with schizophrenia.
- Available Secuado dosage strengths are: 3.8 mg/24 hours (9.0 mg asenapine Maleate per patch), 5.7 mg/24 hours (13.5 mg asenapine Maleate per patch) and 7.6 mg/24 hours (18.0 mg asenapine Maleate per patch).
- The primary evidence supporting the efficacy of Secuado for the treatment of adults with schizophrenia was obtained from three Phase 1 trials and one Phase 3 clinical trial
- Patients treated with Secuado 9.0 mg or 18.0 mg transdermal patches for 6 weeks demonstrated significant improvements in the Positive and Negative Syndrome Scale (PANSS) and the Clinical Global Impression – Severity (CGI-S) scale compared to patients treated with placebo.
- With repeat application of the Secuado patch containing 4.5, 9.0, 13.5, and 18.0 mg asenapine maleate in patients with schizophrenia, plasma concentrations of asenapine reached steady-state in 48 to 72 hours, with minimal peak-trough concentration fluctuations.
- In the Phase 3 clinical trial, Secuado was well-tolerated; adverse events were generally mild to moderate in severity.
- The most common adverse reactions were extrapyramidal disorder, application site reaction, and weight gain.
- Observed skin irritations such as erythema, pruritus, papules, discomfort, pain edema or irritation were reported. Discontinuations due to application site reactions were infrequent ($\leq 0.5\%$ per treatment group).
- The comparative effectiveness of Secuado relative to other antipsychotic drugs has not been studied.

Conclusion

- Secuado (asenapine) transdermal patch is a new SGA approved by the U.S. FDA for the treatment of adult patients with schizophrenia. Secuado has a demonstrated safety, efficacy, and tolerability profile that is supported by evidence from Phase 1 and Phase 3 clinical trials, and it is the first antipsychotic therapy available as an alternative formulation in the U.S.
- Medication non-adherence poses an undue societal and economic burden for this patient population.
- Secuado represents a treatment option to address an unmet need for a more reliable mode of antipsychotic medication administration.
- Secuado transdermal asenapine provides a valuable addition to currently available atypical antipsychotic treatment options, and exhibits the potential to improve clinical, economic, and societal outcomes.