Secuado® (asenapine) – New drug approval

- On October 15, 2019, Noven Pharmaceuticals announced the FDA approval of Secuado (asenapine), for the treatment of adults with schizophrenia.

- Secuado, an atypical antipsychotic, is the first FDA approved transdermal patch formulation for the treatment of schizophrenia.

    — Asenapine is also available as a sublingual tablet (Saphris®). Saphris is approved for schizophrenia and bipolar I disorder.

- The efficacy of Secuado was established, in part, on the basis of efficacy data from trials with the sublingual formulation of asenapine. In addition, the efficacy of Secuado was evaluated in a 6-week, fixed-dose, randomized, double-blind, and placebo-controlled trial of 607 adult patients with schizophrenia. The Positive and Negative Syndrome Scale (PANSS) rating scale was used as the primary efficacy measure.

    — The placebo-subtracted difference in the change from baseline in the PANSS total score was -6.6 (95% CI: -9.81, -3.40) and -4.8 (95% CI: -8.06, -1.64) for Secuado 3.8 mg/24 hours and Secuado 7.6 mg/24 hours, respectively, vs. placebo.

- Secuado carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis.

- Secuado is contraindicated in patients with severe hepatic impairment (Child-Pugh C) and in patients with a history of hypersensitivity reactions to asenapine or any components of the transdermal system.

- Additional warnings and precautions for Secuado include cerebrovascular adverse reactions, including stroke, in elderly patients with dementia-related psychosis; neuroleptic malignant syndrome; tardive dyskinesia; metabolic changes; hypersensitivity reactions; orthostatic hypotension, syncope, and other hemodynamic effects; falls; leukopenia, neutropenia, and agranulocytosis; QT prolongation; hyperprolactinemia; seizures; potential for cognitive and motor impairment; body temperature regulation; dysphagia; external heat; and application site reactions.

- The most common adverse reactions (≥ 5% and at least twice that for placebo) with Secuado use were extrapyramidal disorder, application site reaction, and weight gain.

- The recommended initial dose of Secuado is 3.8 mg/24 hours. The dosage may be increased to 5.7 mg/24 hours or 7.6 mg/24 hours, as needed, after one week. In a short-term, placebo-controlled trial, there was no suggestion of added benefit at a dosage of 7.6 mg/24 hours, on average, but there was an increase in certain adverse reactions.

    — Secuado transdermal system is applied once daily. Each Secuado transdermal system should be worn for 24 hours only.
    — Secuado should be applied to one of the following sites: the hip, abdomen, upper arm, or upper back area.
    — The safety of doses above 7.6 mg/24 hours has not been evaluated in clinical studies.

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- Noven Pharmaceuticals' launch plans for Secuado are pending. Secuado will be available as 3.8 mg/24 hours, 5.7 mg/24 hours and 7.6 mg/24 hours transdermal systems.