

The Medical Letter[®]

on Drugs and Therapeutics

Volume 63

January 11, 2021

ISSUE No.
1615

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IN BRIEF

An Asenapine Patch (*Secuado*) for Schizophrenia

A transdermal formulation of the second-generation (atypical) antipsychotic asenapine (*Secuado* – Noven) has been approved by the FDA for once-daily treatment of schizophrenia in adults. Asenapine is the first antipsychotic to become available in a transdermal formulation in the US. A twice-daily sublingual tablet formulation of asenapine (*Saphris*) has been available since 2009.

Pronunciation Key

Asenapine: a sen' a peen *Secuado*: seh kue a' doe

FDA approval of transdermal asenapine was based on the results of earlier trials that assessed the efficacy of sublingual asenapine in adults with schizophrenia and on one 6-week, double-blind trial comparing transdermal asenapine to placebo in 607 adult inpatients with schizophrenia. Patients treated with transdermal asenapine had statistically significantly greater improvements from baseline in the Positive and Negative Syndrome Scale (PANSS) score at 6 weeks, the primary endpoint, than those who received placebo (see Table 1). Asenapine was also superior to placebo in the Clinical Global Impressions-Severity (CGI-S) rating scale, the secondary endpoint.¹ Transdermal asenapine has not been compared directly with the sublingual formulation or with any other antipsychotic drug.

Antipsychotic drugs, including asenapine, can cause somnolence, metabolic adverse effects (hyperglycemia, diabetes, dyslipidemia, and weight gain), extrapyramidal

Table 1. Transdermal Asenapine Clinical Trial Results¹

Regimen	PANSS Total Score ²	
	Baseline	Change ³
Asenapine 3.8 mg/24 hrs	97.0	-22.1*
Asenapine 7.6 mg/24 hrs	95.6	-20.4*
Placebo	97.4	-15.5

* Statistically significant vs placebo

1. CDER multi-discipline review. Available at: <https://bit.ly/2WetXdk>.

2. PANSS=Positive and Negative Syndrome Scale, a 30-item scale that measures positive and negative symptoms and general psychopathology, each on a scale of 1 (absent) to 7 (extreme). Total PANSS scores ranged from 30-210, with lower scores indicating improvement.

3. Least-squares mean change from baseline at 6 weeks, the primary endpoint.

Table 2. Dosage and Cost of Sublingual and Transdermal Asenapine

Drug	Some Formulations	Usual Dosage ¹	Cost ²
<i>Saphris</i> (Abbvie)	2.5, 5, 10 mg SL tabs ³	5-10 mg bid ⁴	\$1200.80
<i>Secuado</i> (Noven)	3.8, 5.7, 7.6 mg/24 hrs patches ³	1 patch/24 hrs	1200.00 ⁴

SL = sublingual

1. Usual adult dosage for treatment of schizophrenia.

2. Approximate WAC for 30 days' treatment at the lowest usual adult dosage. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly, December 5, 2020. Reprinted with permission by First Databank, Inc. All rights reserved. ©2020. www.fdbhealth.com/policies/drug-pricing-policy.

3. Asenapine exposures with 3.8 mg/24 hour and 7.6 mg/24 hour patches are similar to those with asenapine SL tablets 5 mg bid and 10 mg bid, respectively.

4. Cost for all strengths is the same.

symptoms, dystonia, tardive dyskinesia, neuroleptic malignant syndrome, hypertension, orthostatic hypotension, falls, leukopenia, neutropenia, QT interval prolongation, and hyperprolactinemia.² Application-site reactions occurred in ~15% of patients treated with transdermal asenapine in the clinical trial. Seizures have occurred with use of sublingual asenapine and theoretically could occur with transdermal asenapine. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.

The initial dosage of *Secuado* is one 3.8-mg patch applied once daily. After 1 week, the dosage can be increased to 5.7 mg/24 hours or 7.6 mg/24 hours. The patch should be applied to clean, dry, intact skin on the upper arm, upper back, abdomen, or hip. The new patch should be applied to a site different from that of the previous patch. If irritation or a burning sensation occurs, the patch should be removed and a new one should be applied at a different site. *Secuado* can be used while showering, but not while swimming or taking a bath. External heat sources should not be applied to the patch because heat can increase drug release and systemic exposure to the drug. Asenapine is contraindicated in patients with severe hepatic impairment (Child-Pugh C). ■

1. L Citrome et al. Efficacy and safety of the asenapine transdermal patch, HP-3070, for schizophrenia: a phase 3, randomized, placebo-controlled, inpatient study. *CNS Spectr* 2020; 25:293.
2. Drugs for psychotic disorders. *Med Lett Drugs Ther* 2016; 58:160.

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