A hypothetical patient.

Secuado® (asenapine) transdermal system

3.8mg/24 hours 5.7mg/24 hours 7.6mg/24 hours

Treatment they can wear

Meet Bobby, the dishwasher

- Bobby, aged 45, is a smoker and has been living with schizophrenia for years
- He started hearing voices in his late teens and left home soon after his diagnosis
- Bobby works as a dishwasher. He wants to keep his job but it is a constant struggle
- His work days are erratic so it's hard to comply with the food and drink restrictions of his current oral medication, and he often skips pills
- Bobby lost his job when he was hospitalized, and it took some time to find his current position
- Taking pills is difficult. But he refuses to take long-acting injectables

Is patch therapy an option?

For adult patients with schizophrenia

CONSIDER SECUADO®

A well-documented atypical antipsychotic in a passive, non-invasive delivery form

- Bioequivalent to twice-daily sublingual asenapine with once daily administration[1]

INDICATION

SECUADO® (asenapine) transdermal system is indicated for the treatment of adults with schizophrenia.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. SECUADO is not approved for the treatment of patients with dementia-related psychosis

Contraindications: Severe hepatic impairment (Child-Pugh C) or a history of hypersensitivity reactions to asenapine or any components of this formulation.

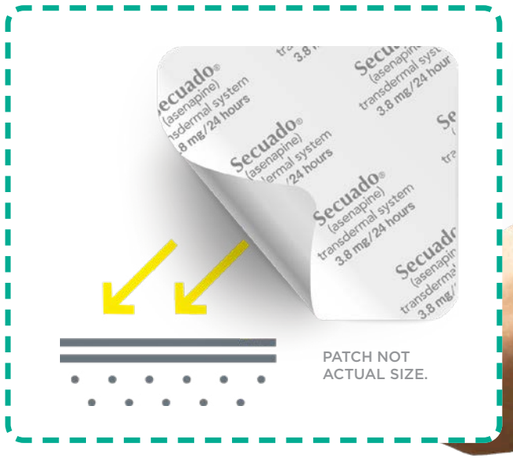
Please see full Important Safety Information on pages 8-9 and please click here for full Prescribing Information, including BOXED WARNING.

For adult patients with schizophrenia
who have aversions to oral and injectable medications

CONSIDER SECUADO® | IT'S ON™

Transdermal delivery for treatment they can wear

- No food or drink considerations[1]
- Once-daily dosing with no adjustments needed for gender, race, smoking status, or renal impairment[1]
- Visual compliance check



IMPORTANT SAFETY INFORMATION, continued

Cerebrovascular Adverse Events, Including Stroke: Elderly subjects with dementia had a higher incidence of stroke (including fatal stroke) and transient ischemic attack in clinical trials with antipsychotic drugs. SECUADO is not approved for the treatment of patients with dementia-related psychosis.

Neuroleptic Malignant Syndrome (NMS): NMS, a potentially fatal symptom complex, has been reported with antipsychotics. NMS can cause hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability. If NMS is suspected, immediately discontinue SECUADO and provide intensive symptomatic treatment and monitoring.

Tardive Dyskinesia (TD): Risk of TD and the likelihood that it will become irreversible increases with the duration of treatment and the cumulative dose of antipsychotic drugs, including SECUADO. TD can develop after relatively brief treatment periods, even at low doses, and may also occur after discontinuation of treatment. Prescribe SECUADO in a manner most likely to reduce the risk of TD. If signs and symptoms of TD appear, drug discontinuation should be considered.

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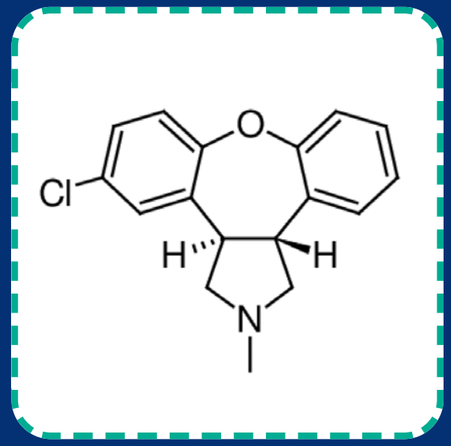
SECUADO® | Delivers asenapine, a well-documented atypical antipsychotic

Sublingual asenapine has been part of the US schizophrenia armamentarium for over 10 years[1]



AUC = area under the curve.

Asenapine is available in a once-daily transdermal patch

- Patch technology achieves bioequivalence with sublingual asenapine twice-daily while allowing once-daily administration[1]
- AUC of asenapine 3.8 mg/24 hours corresponds to sublingual asenapine 5 mg twice daily and the AUC of asenapine 7.6 mg/24 hours corresponds to 10 mg of sublingual asenapine twice a day[1]

IMPORTANT SAFETY INFORMATION, continued

Metabolic Changes: Atypical antipsychotic drugs, including SECUADO, have caused metabolic changes, including the following:

- **Hyperglycemia and Diabetes Mellitus:** Hyperglycemia, in some cases associated with ketoacidosis, hyperosmolar coma, or death, has been reported in patients treated with atypical antipsychotics. Hyperglycemia has been reported in patients treated with sublingual asenapine. Assess fasting plasma glucose before or soon after initiation of treatment, and monitor periodically during long-term treatment.
- **Dyslipidemia:** Atypical antipsychotics cause adverse alterations in lipids. Before or soon after initiation of antipsychotic medication, obtain a baseline fasting lipid profile and monitor periodically during treatment.
- **Weight Gain:** Weight gain has been observed with atypical antipsychotics, including SECUADO. Monitor weight at baseline and frequently thereafter.

Hypersensitivity Reactions: Hypersensitivity reactions, including anaphylaxis, angioedema, hypotension, tachycardia, dyspnea, wheezing, and rash have been reported in patients treated with asenapine, including SECUADO. In several cases, these reactions occurred after the first dose.

Orthostatic Hypotension, Syncope, and Other Hemodynamic Effects: Atypical antipsychotics cause orthostatic hypotension and syncope. The risk is greatest during the initial dose titration and when increasing the dose. Monitor orthostatic vital signs and patients who are vulnerable to hypotension. Use SECUADO cautiously with other drugs that can cause hypotension, bradycardia, respiratory or central nervous system depression. Consider a dose reduction if hypotension occurs.

Falls: SECUADO may cause somnolence, postural hypotension and motor or sensory instability, which may lead to falls, and consequently, fractures or other injuries. For patients with diseases, conditions, or medications that could exacerbate these effects, complete fall risk assessments when initiating antipsychotic treatment and recurrently for patients on long-term antipsychotic therapy.

Please see full Important Safety Information on pages 8-9 and please click here for full Prescribing Information, including BOXED WARNING.

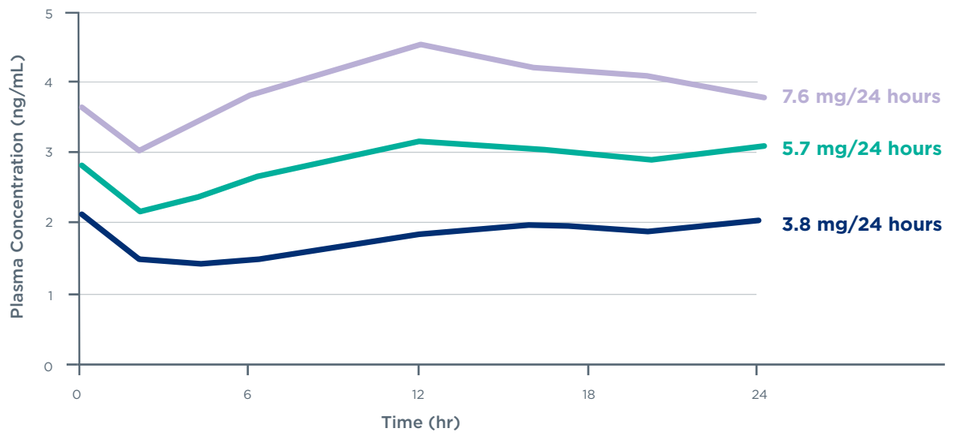
Secuado® (asenapine) transdermal system
3.8mg/24 hours 5.7mg/24 hours 7.6mg/24 hours
Treatment they can wear

CONSIDER SECUADO®

A once-daily asenapine patch with consistent and sustained 24-hour delivery of medication[1,2]

SECUADO provides smooth onset, steady delivery, and low peak to trough ratios[2]

Mean asenapine concentration-time profiles at steady state[2]



Steady-state plasma concentrations are achieved at about 72 hours after the first application of SECUADO; peak to trough ratio is 1.5[2]

- **Pharmacokinetics of asenapine at steady state is dose-proportional over the dosing range 3.8 mg/24 hours to 7.6 mg/24 hours following patch application[1]**
- **Avoid exposing SECUADO to direct external heat sources (eg, heating pads) during wear because both the rate and extent of absorption are increased[1]**

IMPORTANT SAFETY INFORMATION, continued

Leukopenia, Neutropenia, and Agranulocytosis: Leukopenia, neutropenia, and agranulocytosis (including fatal cases) have been reported with antipsychotics, including asenapine. Monitor complete blood count in patients with pre-existing low white blood cell count (WBC) or absolute neutrophil count or history of drug-induced leukopenia or neutropenia. Discontinue SECUADO at the first sign of a clinically significant decline in WBC and in severely neutropenic patients.

QT Prolongation: Sublingual asenapine was associated with increases in QTc interval from 2 to 5 msec versus placebo. There were no reports of QT prolongation exceeding 500 msec for SECUADO and placebo. The use of SECUADO should be avoided in patients with a history of cardiac arrhythmias and in circumstances that may increase the risk of the occurrence of torsade de pointes and/or sudden death in association with the use of drugs that prolong the QTc interval.

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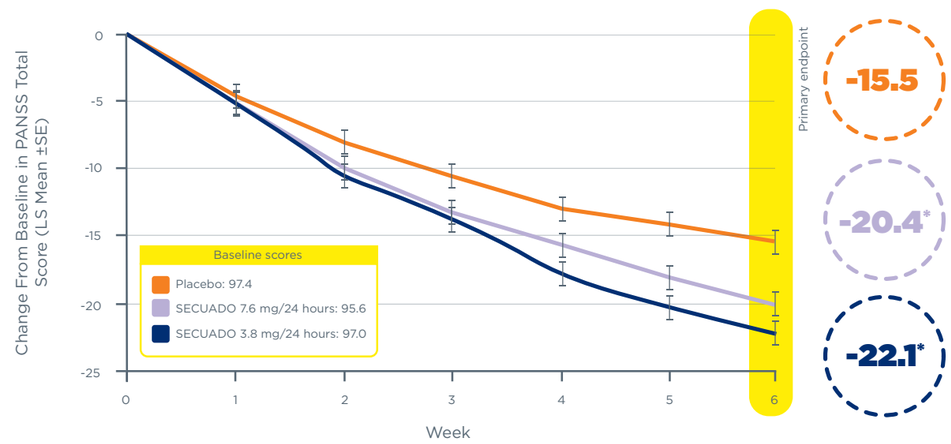
SECUADO® | Proven efficacy

Significant reduction in PANSS total score at week 6 (n=607)[1]

PANSS total score improvement vs placebo[1,3]



*Statistically significant after multiplicity adjustments, $P < .05$.[2]

The efficacy of SECUADO was evaluated in a 6-week, fixed-dose, randomized, double-blind, placebo-controlled trial (Study 1; NCT 02876900) of adult patients who met *DSM-IV*® criteria for schizophrenia. The PANSS and CGI-S rating scales were used as the primary and key secondary efficacy measures, respectively, for assessing psychiatric signs and symptoms in each trial.[1] PANSS is a 30-item scale that measures positive symptoms of schizophrenia (7 items), negative symptoms of schizophrenia (7 items), and general psychopathology (16 items), each rated on a scale of 1 (absent) to 7 (extreme); total PANSS scores range from 30 to 210. CGI-S is a validated clinician-related scale that measures the patient's current illness state and overall clinical state on a 1-point (normal, not at all ill) to 7-point (extremely ill) scale, based on the rater's total clinical experience with this population.[1]
DSM-IV = Diagnostic and Statistical Manual of Mental Disorders (Fourth Edition); LS = least squares; PANSS = Positive and Negative Syndrome Scale; SE = standard error.
DSM-IV® is a registered trademark of the American Psychiatric Association.

- **Both doses of SECUADO® were also statistically superior to placebo for Clinical Global Impressions-Severity (CGI-S)[1]**
- **The efficacy of SECUADO was established, in part, based on data from trials with the sublingual formulation of asenapine[1]**

IMPORTANT SAFETY INFORMATION, continued

Hyperprolactinemia: SECUADO can elevate prolactin levels and the elevation can persist during chronic administration. Long-standing hyperprolactinemia when associated with hypogonadism may lead to decreased bone density in both female and male subjects.

Seizures: Use SECUADO with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Potential for Cognitive and Motor Impairment: Somnolence was reported in patients treated with SECUADO. Caution patients about operating hazardous machinery, including motor vehicles, until they are reasonably certain that SECUADO does not affect them adversely.

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Treatment they can wear

CONSIDER SECUADO®

Established safety and tolerability

Commonly observed adverse reactions (incidence ≥5% and at least twice the rate of placebo) were extrapyramidal disorder, application site reaction, and weight gain[1]

Adverse reactions in ≥2% of patients at either SECUADO dose, occurring at greater incidence vs placebo (6-week trial)[1]

System/Organ Class Preferred Term	Placebo (N=206) %	SECUADO 3.8 mg/24 hrs (N=204) %	SECUADO 7.6 mg/24 hrs (N=204) %
Gastrointestinal Disorders			
Constipation	4	5	4
Dyspepsia	1	1	3
Diarrhea	1	3	1
General Disorders			
Application site reactions*	4	15	14
Investigations			
Blood glucose increased*	1	3	1
Weight increased	2	4	6
Hepatic enzyme increased*	0	2	2
Infections and Infestations			
Nasopharyngitis	2	3	1
Upper respiratory tract infection	2	3	1
Metabolism and Nutrition Disorders			
Increased appetite	0	3	1
Nervous System Disorders			
Headache	6	9	9
Extrapyramidal symptoms*	2	8	13
Akathisia	2	4	4
Somnolence*	1	4	3
Dystonia	0	1	3
Vascular Disorders			
Hypertension*	1	2	2

*The following terms were combined: Application site reactions includes application site dermatitis, discoloration, discomfort, dryness, edema, erythema, exfoliation, induration, irritation, pain, papules, pruritus, and reaction. Blood glucose increased includes blood glucose increased, blood insulin increased, glycosylated hemoglobin increased, hyperglycemia, type 2 diabetes mellitus, diabetes mellitus, and hyperinsulinemia. Hepatic enzyme increased includes hepatic enzyme increased, alanine aminotransferase increased, aspartate aminotransferase increased, and gamma-glutamyltransferase increased. Extrapyramidal symptoms includes dyskinesia, dystonia, extrapyramidal disorder, parkinsonism, tardive dyskinesia, muscle spasm, and musculoskeletal stiffness. Somnolence includes somnolence, sedation, lethargy, and hypersomnia. Hypertension includes hypertension, blood pressure increased, diastolic hypertension, and hypertensive crisis.

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SECUADO® | Established safety and tolerability

SECUADO had a discontinuation rate similar to placebo[1]

In this trial, % patients	Placebo (n=206)	SECUADO 3.8 mg/24 hours (n=204)	SECUADO 7.6mg/24 hours (n=204)
Discontinued due to adverse reactions	6.8%	4.9%	7.8%
The adverse reaction that most commonly led to discontinuation among patients treated with SECUADO in this trial was akathisia[1]			
Discontinued due to akathisia	0.5% (1/206)	0% (0/204)	1.5% (3/204)

Selected effects on weight, appetite, and blood glucose seen in ≥2% of patients at either SECUADO dose[1]

In this trial, % patients	Placebo (n=206)	SECUADO 3.8 mg/24 hours	SECUADO 7.6mg/24 hours
Weight increased	2%	4%	6%
Appetite increased	0%	3%	1%
Blood glucose increased†	1%	3%	1%

†Blood glucose increased includes blood glucose increased, blood insulin increased, glycosylated hemoglobin increased, hyperglycemia, type 2 diabetes mellitus, diabetes mellitus, and hyperinsulinemia.

See full table of adverse reactions on previous page.

- **The tolerability and safety profiles of sublingual asenapine were established in a 52-week, double-blind, comparator-controlled adult trial that included primarily patients with schizophrenia[1]**

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Body Temperature Regulation: Use SECUADO with caution in patients who will experience conditions that increase body temperature (strenuous exercise, extreme heat, dehydration and concomitant anticholinergics).

Dysphagia: SECUADO should be used cautiously in patients at risk for aspiration. Esophageal dysmotility and aspiration have been associated with antipsychotic drug use.

External Heat: Avoid direct external heat sources while wearing SECUADO.

Application Site Reactions: During wear time or immediately after removal of SECUADO, local skin irritation may occur. Instruct patients to select a different patch application site each day to limit the occurrence of skin irritation.

Adverse Reactions: Commonly observed adverse reactions (incidence ≥5% and at least twice the rate of placebo) were extrapyramidal disorder, application site reaction and weight gain.

Drug Interactions: Monitor blood pressure and adjust antihypertensive drugs when taken with SECUADO. Based on clinical response, SECUADO dose reduction may be necessary when used with strong CYP1A2 inhibitors (fluvoxamine). Reduce paroxetine (CYP2D6 substrate and inhibitor) dose by half when taken with SECUADO.

Pregnancy: Studies have not been conducted with SECUADO in pregnant women. Advise patients to notify their healthcare provider of a known or suspected pregnancy. The National Pregnancy Registry for Atypical Antipsychotics monitors pregnancy outcomes in women exposed to antipsychotics, including SECUADO, during pregnancy. For information, contact 1-866-961-2388 or http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/.

To report suspected Adverse Reactions, contact Noven at 800-455-8070 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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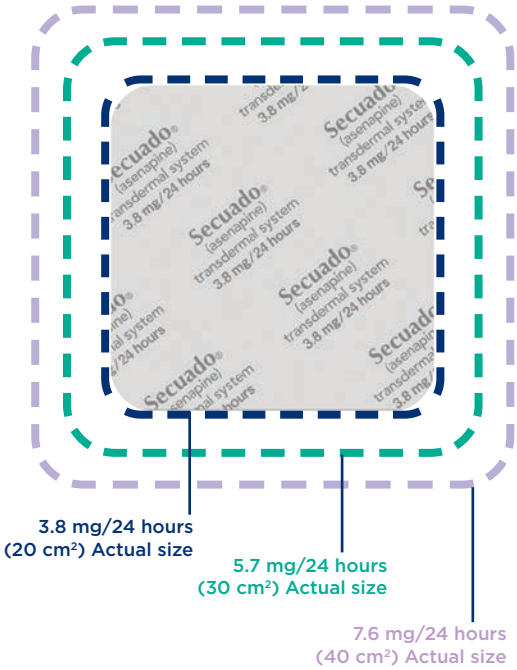
Treatment they can wear

SECUADO® | IT'S ON™

For adult patients with schizophrenia who have aversions to oral and injectable medications

CONSIDER SECUADO—Empower your patients with treatment they can wear

- Three dosing strengths, one convenient delivery form
- Patients should be started and can be maintained on the 3.8 mg/24 hours patch[1]
- Dosage may be increased to 5.7 mg/24 hours or 7.6 mg/24 hours, if needed, after 1 week[1]
- Patients have a choice of application sites (rotate daily between upper arm, upper back, abdomen and hip)
- The patch may be applied to the left or right side



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References: 1. SECUADO® (asenapine) transdermal system [prescribing information]. Miami, FL: Noven Therapeutics, LLC; October 2019. **2.** Data on file. Noven Pharmaceuticals, Inc. **3.** Citrome L, Walling D, Zeni C, et al. Efficacy and safety of the asenapine transdermal patch, HP-3070, for schizophrenia: a phase 3 randomized, placebo-controlled, inpatient study. *J Clin Psych.* 2021;82(1):20m13602.

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SDO-2732-16 08/2022

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Treatment they can wear