

PRESS RELEASE

Notice of Extended Shelf Life for SECUADO® (asenapine) Transdermal System

Miami, FL and Jersey City, NJ – October 8, 2025 -- Noven Pharmaceuticals, Inc., a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc., is pleased to announce that the shelf life of SECUADO® (asenapine) Transdermal System has been extended from 24-month to 30-month, beginning this fall. SECUADO is the first-and-only transdermal patch formulation for the treatment of adults with schizophrenia approved by the U.S. Food and Drug Administration (FDA). The lot numbers of the initial cartons with the newly extended shelf life, along with their new expiration dates, are as follows:

	Lot number	Expiration Date	Estimated Shipment from Our Facility
SECUADO® 3.8mg/24 hours	C51A1	10/31/2027	Week of 9/22/2025
SECUADO® 5.7mg/24 hours	C51A2	10/31/2027	Already in circulation
SECUADO® 7.6mg/24 hours	C61A3	12/25/2027	Week of 10/13/2025

Due to inventory levels at various distribution stages, both the current product and the revised product may be present in the market simultaneously.

What is SECUADO®?

SECUADO is a prescription medicine used to treat adults with schizophrenia. SECUADO is a transdermal system (patch) you apply to your skin. It is not known if SECUADO is safe and effective in children less than 18 years of age with schizophrenia.

IMPORTANT SAFETY INFORMATION

SECUADO may cause serious side effects, including:

- **Increased risk of death in elderly people with dementia-related psychosis. Medicines like SECUADO can raise the risk of death in elderly people who have lost touch with reality (psychosis) due to confusion and memory loss (dementia). SECUADO is not approved for the treatment of people with dementia-related psychosis.**

- **Stroke (cerebrovascular problems) in elderly people with dementia related psychosis that can lead to death.**
- **Neuroleptic Malignant Syndrome (NMS): a serious condition that can lead to death.**
Immediately remove the patch. Call your healthcare provider or go to the nearest hospital emergency room right away if you have some or all of the following: high fever, confusion, stiff muscles, increased sweating and changes in your breathing, heart rate and blood pressure.
- **Uncontrolled body movements (tardive dyskinesia).** SECUADO may cause movements that you cannot control in your face, tongue, or other body parts. Tardive dyskinesia may not go away, even if you stop taking SECUADO. Tardive dyskinesia may also start after you stop taking SECUADO.
- **Problems with your metabolism such as:**
 - **High blood sugar (hyperglycemia) and diabetes.** Increases in blood sugar can happen in some people who take SECUADO. **Call your healthcare provider if you have any of these symptoms of high blood sugar during treatment with SECUADO:**
 - Feel very thirsty or very hungry
 - Feel sick to your stomach
 - Feel weak or tired
 - Need to urinate more than usual
 - Feel confused, or your breath smells fruity
 - **Increased fat levels (cholesterol and triglycerides) in your blood**
 - **Weight gain.** You and your healthcare provider should check your weight regularly during treatment with SECUADO.
- **Allergic reactions.** You may observe rash, decreased blood pressure or a fast heart rate.
- **Decreased blood pressure (orthostatic hypotension).** You may feel lightheaded or faint when you rise too quickly from a sitting or lying position.
- **Falls.** SECUADO may make you sleepy or dizzy, may cause a decrease in your blood pressure when changing position, and can slow your thinking which may lead to falls.
- **Low white blood cell count.** Your healthcare provider may do blood tests during the first few months of treatment with SECUADO.
- **Irregular heartbeat** or a heartbeat that does not feel normal (QT prolongation)
- **Increased prolactin levels in your blood (hyperprolactinemia).** Your healthcare provider may do blood tests to check your prolactin levels during treatment with SECUADO.
- **Seizures (convulsions)**

- **Impaired thinking and motor skills.** Use caution when operating heavy machinery when using SECUADO.
- **Problems controlling your body temperature so that you feel too warm**
- **Difficulty swallowing**
- **External heat.** Avoid exposing SECUADO to direct external heat sources such as hair dryers, heating pads, electric blankets, heated water beds, etc.
- **Application site reactions. Increased skin irritation may occur if SECUADO is applied for a longer period than instructed or if the same application site is used repeatedly. Use a different application site each day to decrease skin reactions.** If skin reactions continue or spread beyond the application site, tell your healthcare provider. Symptoms of application site reactions may include:
 - Redness
 - Itching
 - Irritation
 - Pimple-like raised skin
 - Pain of the skin
 - Swelling

Do not use SECUADO if you:

- Are allergic to asenapine or any other ingredients in SECUADO
- Have severe liver impairment

Before you use SECUADO, tell your healthcare provider about all of your medical conditions, including if you have or have had:

- Heart problems or stroke
- Low or high blood pressure
- Diabetes or high blood sugar, or have a family history of diabetes or high blood sugar
- High levels of total cholesterol or triglycerides
- High prolactin levels
- Low white blood cell count
- Seizures
- Liver problems

Tell your healthcare provider if you become pregnant or think you are pregnant during treatment with SECUADO. It is not known if SECUADO will harm your unborn baby.

- If you become pregnant during treatment with SECUADO, talk to your healthcare provider about registering with the National Pregnancy Registry for Atypical Antipsychotics. You can register by calling [1-866-961-2388](tel:1-866-961-2388) or go to <https://womensmentalhealth.org/research/pregnancyregistry/>.

Talk to your healthcare provider about the best way to feed your baby during treatment with SECUADO. It is not known if SECUADO passes into your breast milk.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SECUADO and other medicines may affect each other causing possible serious side effects. SECUADO may affect the way other medicines work, and other medicines may affect how SECUADO works.

The most common side effects of SECUADO include:

- Restlessness, difficulty moving, muscle stiffness, tremor
- Skin irritation where the patch is placed
- Weight gain

Tell your healthcare provider if you have any side effects that bothers you or does not go away. These are not all the possible side effects of SECUADO.

[Please click here for full Prescribing Information, including BOXED WARNING.](#)

To report suspected Adverse Reactions, contact Noven at [800-455-8070](tel:800-455-8070) or FDA at [1-800-FDA-1088](tel:1-800-FDA-1088) or www.fda.gov/medwatch.

For information call [800-455-8070](tel:800-455-8070). Please see our [Privacy Policy](#) for more information.

About Noven

Noven Pharmaceuticals, Inc. is a specialty pharmaceutical company engaged in the research, development, manufacturing, marketing and sale of prescription pharmaceutical products. Noven's mission is to develop and offer pharmaceutical products that meaningfully benefit patients around the world, with a commitment to advancing patient care through transdermal drug delivery. Noven is a stand-alone operating subsidiary of Japan-based Hisamitsu Pharmaceutical Co., Inc., serving as Hisamitsu's U.S. platform in prescription pharmaceuticals, and helping Hisamitsu bring the benefits of patch therapy to the world. For more information about Noven, visit www.noven.com. For information about Hisamitsu, visit www.hisamitsu.co.jp/english.