

Instructions for Use

SECUADO® (seh kue a' doe) (asenapine) transdermal system

Read this Instructions for Use before you start using the SECUADO transdermal system (patch) and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

IMPORTANT INFORMATION:

- The SECUADO transdermal system (patch) is for use on the skin only (transdermal).
- Do not cut the pouch open until you are ready to apply the patch.
- You should apply only 1 SECUADO patch to 1 application site every 24 hours. **The patch should only be worn for 24 hours.** Do not wear the patch longer than 24 hours.
- Avoid bathing or swimming while wearing the patch. Swimming or bathing may cause the patch to fall off. You may shower.
- Avoid exposing the patch application site to direct heat sources such as hair dryers, heating pads, electric blankets, or heated water beds.
- If your skin feels irritated or feels like it is burning after you apply the patch, remove the patch and apply a new patch to a new application site.

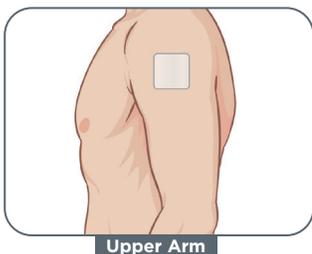
Please read Important Safety Information on pages 5 and 6 and see SECUADO.com for full Prescribing Information, including **BOXED WARNING**.

Applying your SECUADO patch:

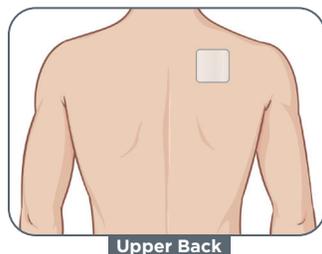
- Change (rotate) your patch application site every time you apply a new patch. Changing your application site every time you apply a patch will help to lessen your chances of developing skin irritation at the application site. **Do not use the same application site 2 times in a row.**
- The application site you choose should be clean, dry, and intact. Do not apply the patch on skin that has cuts, scrapes, burns, rashes, redness, or other skin problems.
- The application site you choose should be **hairless or nearly hairless**. If there is a lot of hair, use scissors to clip the hair as close to the skin as possible. **Do not shave the application site.**
- Do not apply the patch on skin that has oils, lotions, or powders on it.
- Do not apply the patch to areas of your skin where you wear tight clothing, such as waistbands, bras, or tank top straps.

Step 1

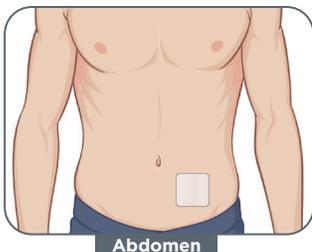
- **Always remove the used patch before applying a new one.** You should only wear 1 patch at a time.
- **Choose 1 application site to apply 1 patch.**
- **The application site you may choose should be one of the approved sites listed. Apply the patch to the left or right:**
 - o upper arm
 - o upper back
 - o stomach area (abdomen)
 - o hip



OR



OR



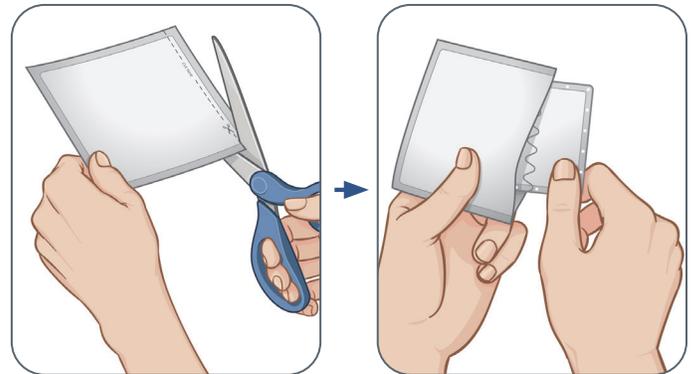
OR



Step 2

When you are ready to apply your patch, use scissors and carefully cut the protective pouch along the dashed line to open the pouch and remove the patch. **Do not cut the SECUADO patch.**

- Do not use the patch if it is cut or damaged or if the seal on the pouch is broken. Throw it away and get a new one.
- Apply the patch right away after removing it from the pouch.



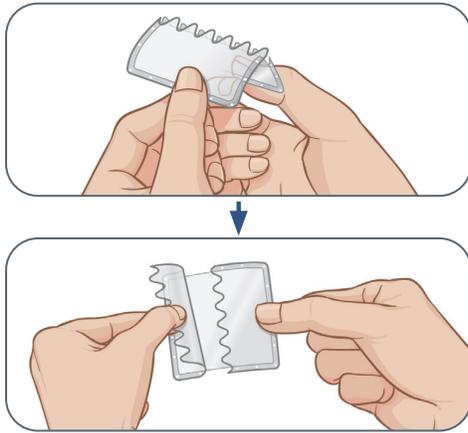
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Step 3

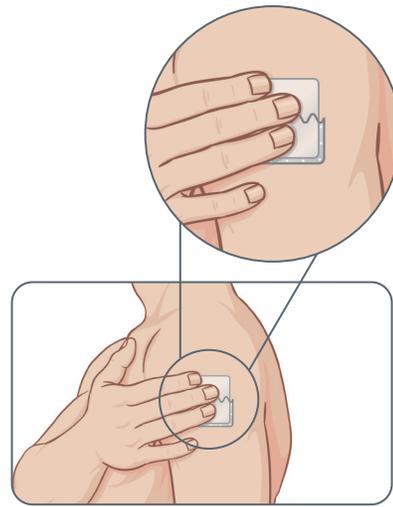
Hold the patch with the protective liner facing you. Bend the patch along the wave-shaped line in the middle of the protective liner. Slowly peel **half** of the protective liner off your patch.

- **Do not** touch the sticky side of the patch.



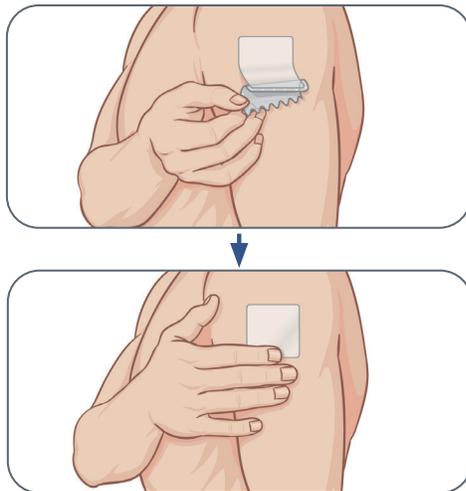
Step 4

Holding the other half of the protective liner, apply the sticky half of the patch to the application site you chose and **smooth it down** with your fingers.



Step 5

Hold the edge of the remaining half of the protective liner, then slowly peel it away and **smooth the patch down** onto your skin with your fingers.

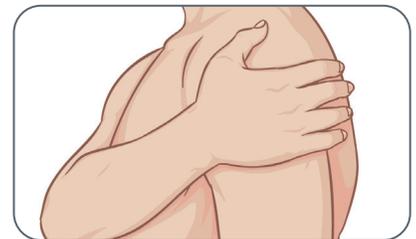


Step 6

Press and hold the patch firmly with the palm of your hand to make sure the patch and edges are sticking to your skin.

- Check the patch regularly during the day to make sure the patch is still firmly attached to your skin, especially after showering, using the bathroom, undressing, changing clothes, sleeping, or sweating.
- If the patch edges lift off your skin, you should smooth down edges with your fingers, **press and hold** the patch firmly with the palm of your hand.
- **If your patch falls off, do not reapply the same patch.**

Choose a new application site and repeat Steps 1 through 7 to apply a new SECUADO patch. Then, follow your normal schedule for changing the patch.



Step 7

Wash your hands with soap and water after applying the patch.



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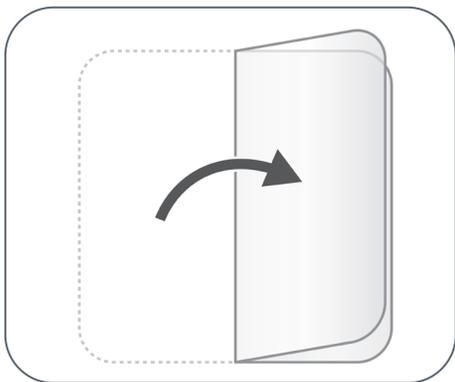
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Removing and disposing of your used SECUADO patch:

Step 8

After you have worn the patch for 24 hours, remove the used patch from your skin and **fold it in half so that the sticky sides stick together.**

- Your used patch still has some medicine and should be **folded**.
- If the patch is hard to remove from the skin, gently apply an oil-based product (petroleum jelly, olive oil, or mineral oil) to the patch edges.
- If any adhesive (glue) remains on the skin after you remove the patch, apply an oil-based product or lotion to help with the removal.



Step 9

Safely throw away the used **folded** patch in the trash right away so that children and pets cannot reach it.



Step 10

Wash your hands with soap and water after removing the patch.



How should I store SECUADO patch?

- Store SECUADO patches at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep SECUADO patches and all medicines out of the reach of children.**

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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.

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IMPORTANT SAFETY INFORMATION, Continued

- **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:

- o Redness
- o Itching
- o Irritation
- o Pimple-like raised skin
- o Pain of the skin
- o 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.

- o 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 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.

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

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