

MEDICATION GUIDE Scopolamine (skoe-POL-a-meen) Transdermal System
Read this Medication Guide before you start using scopolamine transdermal system and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.
What is scopolamine transdermal system? Scopolamine transdermal system is a prescription medicine used for adults to help prevent: <ul style="list-style-type: none">nausea and vomiting from motion sicknessnausea and vomiting from anesthesia or taking opioid pain medicines after surgery It is not known if scopolamine transdermal system is safe or effective in children.
Who should not use scopolamine transdermal system? Do not use scopolamine transdermal system if you: <ul style="list-style-type: none">have an eye problem called angle closure glaucoma.are allergic to scopolamine, belladonna alkaloids or any of the ingredients in scopolamine transdermal system. See the end of this leaflet for a list of the ingredients in scopolamine transdermal system. Ask your doctor if you are not sure.
What should I tell my doctor before using scopolamine transdermal system? Before you use scopolamine transdermal system, tell your doctor about all of your medical conditions, including if you: <ul style="list-style-type: none">have glaucoma (increased pressure in the eye).have a history of seizures or psychosis.have problems with your stomach or intestines.have trouble urinating.are scheduled to have a gastric secretion test.have liver or kidney problems.are pregnant or plan to become pregnant. It is not known if scopolamine can harm your unborn baby.are breastfeeding or plan to breastfeed. Scopolamine can pass into your breast milk and may harm your baby. Talk to your doctor about the best way to feed your baby if you use scopolamine transdermal system. Tell your doctor about all the medicines you take , including prescription and over-the-counter medicines, vitamins and herbal supplements. Scopolamine transdermal system may affect the way other medicines work, and other medicines may affect how scopolamine transdermal system works. Medicines that you take by mouth may not be absorbed well while you use scopolamine transdermal system. Especially tell your doctor if you take: <ul style="list-style-type: none">a sedative, hypnotic, opioid or anxiolytic (medicines that make you sleepy)an antidepressant medicinean anticholinergic medicine, such as an allergy or cold medicine, a medicine to treat bladder or bowel spasms, certain asthma medicines, or other medicines for motion sickness Ask your doctor if you are not sure if your medicine is one that is listed above. Know the medicines you take. Keep a list of them and show it to your doctor or pharmacist when you get a new medicine.
How should I use scopolamine transdermal system? <ul style="list-style-type: none">See the detailed Instructions for Use for information about how to use scopolamine transdermal system at the end of this Medication Guide.It is important that you apply scopolamine transdermal system exactly as your doctor tells you to.

- Your doctor may change your scopolamine transdermal system dose. **Do not** change your scopolamine transdermal system dose without talking to your doctor.
- Wear only one scopolamine transdermal system at any time.
- If you use too much scopolamine transdermal system, call your doctor or Poison Control Center at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What should I avoid while using scopolamine transdermal system?

- You should not drink alcohol while using scopolamine transdermal system. It can increase your chances of having serious side effects.
- You should not drive, operate heavy machinery, or do other dangerous activities until you know how scopolamine transdermal system affects you.
- You should not use scopolamine transdermal system during a Magnetic Resonance Imaging scan (MRI). Remove scopolamine transdermal system before undergoing an MRI. It can cause your skin to burn.
- You should be careful if you use scopolamine transdermal system while you participate in watersports because you may feel lost or confused (disoriented).
- Limit contact with water while swimming and bathing because scopolamine transdermal system may fall off. If scopolamine transdermal system falls off, throw it away and apply a new one on the hairless area behind your other ear.

What are the possible side effects of scopolamine transdermal system? Scopolamine transdermal system may cause serious side effects, including:

- angle closure glaucoma.** If you have open angle glaucoma and use scopolamine transdermal system, remove scopolamine transdermal system and call a doctor right away if you feel pain or discomfort, have blurred vision, or see halos or colored images around lights and reddening of your eyes.
- worsening of seizures.** Tell your doctor about any worsening of seizures while using scopolamine transdermal system.
- an unusual reaction called acute psychosis.** Tell your doctor if you have any of these symptoms:
 - confusion
 - agitation
 - rambling speech
 - hallucinations (seeing or hearing things that are not there)
 - paranoid behaviors and delusions (false belief in something)
- worsening of your preeclampsia during pregnancy.** Some pregnant women with severe preeclampsia have had seizures after getting scopolamine by injection in the muscle (intramuscular) or injection in the vein (intravenous).
- difficulty urinating.**
- difficulties in food passing from the stomach to the small intestines, which may cause abdominal pain, nausea or vomiting.**
- withdrawal symptoms after removing scopolamine transdermal system after using it for several days.** Some people may have certain symptoms such as difficulty with balance, dizziness, nausea, vomiting, stomach cramps, sweating, confusion, muscle weakness, low heart rate or low blood pressure that could start 24 hours or more after removing scopolamine transdermal system. Call your doctor right away if your symptoms become severe.
- temporary increase in the size of your pupil and blurry vision**, especially if scopolamine transdermal system comes in contact with your eyes.
- skin burns at the site of scopolamine transdermal system.** This can happen during a medical test called a Magnetic Resonance Imaging scan (MRI). Scopolamine transdermal system contains aluminum and should be removed from your skin before you have an MRI.

The most common side effects of using scopolamine transdermal system include:

- dry mouth
- blurred vision or eye problems
- feeling sleepy or drowsy
- disorientation (confusion)
- dizziness
- feeling agitated or irritable
- pharyngitis (sore throat)

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of scopolamine transdermal system.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of scopolamine transdermal system.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use scopolamine transdermal system for a condition for which it was not prescribed. Do not give scopolamine transdermal system to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or doctor for information about scopolamine transdermal system that is written for health professionals.

What are the ingredients in scopolamine transdermal system?
Active ingredient: scopolamine
Inactive ingredients: Aluminized polyester backing film, acrylic adhesive, siliconized PET release liner, ethylene vinyl acetate membrane and isopropyl myristate. The brown imprinting ink contains FD&C yellow no. 6 aluminum lake, polyamide resin, polytetrafluoroethylene, polyethylene wax, carbon black and quinacridone red pigment.
For more information, call **Ingenus Pharmaceuticals, LLC at 1-877-748-1970.**

**INSTRUCTIONS FOR USE
Scopolamine (skoe-POL-a-meen) Transdermal System**

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

Information about scopolamine transdermal system:

- Scopolamine transdermal system is a tan-colored, circle shaped transdermal system (patch) with “Scopolamine 1 mg/3 days” printed on it.
- Wear only one scopolamine transdermal system at any time.
- Do not** cut the scopolamine transdermal system.

To help prevent nausea and vomiting from motion sickness:

- Apply one scopolamine transdermal system to your skin on a hairless area behind one ear at least 4 hours before the activity to prevent nausea and vomiting.
- If the treatment is needed for longer than 3 days, remove scopolamine transdermal system from the hairless area behind your ear. Get a new scopolamine transdermal system and place it on the hairless area behind your other ear.

To help prevent nausea and vomiting after surgery:

- Follow your doctor's instructions about when to apply scopolamine transdermal system before your scheduled surgery.
- Scopolamine transdermal system should be left in place for 24 hours after surgery. After 24 hours, scopolamine transdermal system should be removed and thrown away.

How to use scopolamine transdermal system:

Inside the scopolamine transdermal system package, you will find one scopolamine transdermal system. An imprinted, tan backing membrane with a metallic (silver) sticky surface is adhered to a clear, disposable plastic release liner with stipples (See Figure 1).

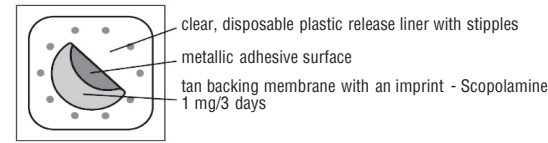


Figure 1

- Select a hairless area of skin behind one of your ears. Avoid areas on your skin that may have cuts, pain or tenderness. Wipe the area of your skin with a clean, dry tissue.
- Tear along the dashed line on the scopolamine transdermal system package to open (See Figure 2).

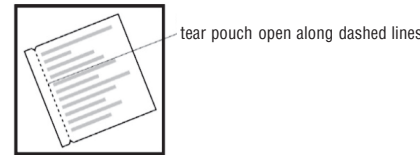


Figure 2

- Remove the clear plastic backing (disposable release liner with stipples) from the tan-colored round scopolamine transdermal system (See Figure 3).



Figure 3

- Do not** touch the metallic adhesive (sticky) surface on scopolamine transdermal system with your hands (See Figure 4).

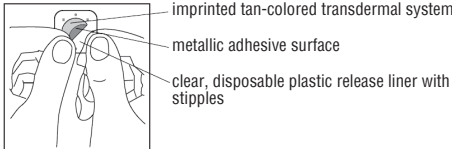


Figure 4

- Apply the metallic adhesive surface of scopolamine transdermal system firmly to the dry area of skin behind your ear. The imprinted, tan-colored side of the scopolamine transdermal system should be facing up and showing (See Figure 5). Wash your hands with soap and water right away after applying scopolamine transdermal system, so that any medicine from the scopolamine transdermal system that gets on your hands will not get into your eyes.

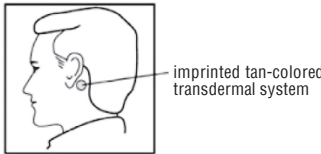


Figure 5

How to remove scopolamine transdermal system:

After removing scopolamine transdermal system, be sure to wash your hands and the area behind your ear thoroughly with soap and water. Please note that the used scopolamine transdermal system will still contain some of the active ingredient after use. To avoid accidental contact or ingestion by children, pets or others, fold the used scopolamine transdermal system in half with the sticky side together. Throw away (dispose of) scopolamine transdermal system in the household trash out of the reach of children, pets or others.

How should I store scopolamine transdermal system?

- Store scopolamine transdermal system at room temperature between 68°F to 77°F (20°C to 25°C) until you are ready to use it.
- Store scopolamine transdermal system in an upright position.
- Do not bend or roll scopolamine transdermal system

Keep scopolamine transdermal system and all medicines out of reach of children. The Medication Guide and Instructions for Use have been approved by the U.S. Food and Drug Administration.

Manufactured for:
Ingenus Pharmaceuticals, LLC
Orlando, FL 32839-6408

Rev. 05/2023

Rev-01

