

PATIENT INFORMATION

TRANSDERM SCÖP (trans-derm sköp)
(scopolamine transdermal system)

Read this Patient Information before you start using TRANSDERM SCÖP 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 TRANSDERM SCÖP?

TRANSDERM SCÖP is a prescription medicine used for adults to help prevent:

- nausea and vomiting from motion sickness
- nausea and vomiting from anesthesia or taking opioid pain medicines after surgery

It is not known if TRANSDERM SCÖP is safe and effective in children.

Who should not use TRANSDERM SCÖP?

Do not use TRANSDERM SCÖP if you:

- have an eye problem called angle closure glaucoma.
- are allergic to scopolamine, belladonna alkaloids or any of the ingredients in TRANSDERM SCÖP. See the end of this Patient Information leaflet for a list of the ingredients in TRANSDERM SCÖP. Ask your doctor if you are not sure.

What should I tell my doctor before using TRANSDERM SCÖP?

Before you use TRANSDERM SCÖP, tell your doctor about all of your medical conditions, including if you:

- 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 TRANSDERM SCÖP can harm your unborn baby.
- are breastfeeding or plan to breastfeed. TRANSDERM SCÖP can pass into your breast milk. Talk to your doctor about the best way to feed your baby if you use TRANSDERM SCÖP.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. TRANSDERM SCÖP may affect the way other medicines work, and other medicines may affect how TRANSDERM SCÖP works. Medicines that you take by mouth may not be absorbed well while you use TRANSDERM SCÖP.

Especially tell your doctor if you take:

- a sedative, hypnotic, opioid or anxiolytic (medicines that make you sleepy)
- an antidepressant medicine
- an 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 TRANSDERM SCÖP?

- See the detailed **Instructions for Use** for information about how to use TRANSDERM SCÖP at the end of this Patient Information leaflet.
- It is important that you apply TRANSDERM SCÖP exactly as your doctor tells you to.
- Your doctor may change your TRANSDERM SCÖP dose. **Do not** change your TRANSDERM SCÖP dose without talking to your doctor.
- Wear only one TRANSDERM SCÖP at any time.
- If you use too much TRANSDERM SCÖP, call your doctor or Poison Help line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What should I avoid while using TRANSDERM SCÖP?

- You should not drink alcohol while using TRANSDERM SCÖP. 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 TRANSDERM SCÖP affects you.
- You should not use TRANSDERM SCÖP during a Magnetic Resonance Imaging scan (MRI). Remove TRANSDERM SCÖP before undergoing an MRI. It can cause your skin to burn.
- You should be careful if you use TRANSDERM SCÖP while you participate in watersports because you may feel lost or confused (disoriented).

- Limit contact with water while swimming and bathing because TRANSDERM SCÖP may fall off. If TRANSDERM SCÖP 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 TRANSDERM SCÖP?

TRANSDERM SCÖP may cause serious side effects, including:

- **angle closure glaucoma.** If you have open angle glaucoma and use TRANSDERM SCÖP, remove TRANSDERM SCÖP 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 TRANSDERM SCÖP.
- **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)If you experience any of the above symptoms, your doctor may stop your treatment with TRANSDERM SCÖP. If your symptoms continue and they are severe, get medical help.
- **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 TRANSDERM SCÖP 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 TRANSDERM SCÖP. Call your doctor right away if your symptoms become severe.
- **temporary increase in the size of your pupil and blurry vision,** especially if TRANSDERM SCÖP comes in contact with your eyes.
- **skin burns at the site of TRANSDERM SCÖP.** This can happen during a medical test called a Magnetic Resonance Imaging scan (MRI). TRANSDERM SCÖP contains aluminum and should be removed from your skin before you have an MRI.

The most common side effects of using TRANSDERM SCÖP 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 TRANSDERM SCÖP.

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 TRANSDERM SCÖP.

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use TRANSDERM SCÖP for a condition for which it was not prescribed. Do not give TRANSDERM SCÖP 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 TRANSDERM SCÖP that is written for health professionals.

What are the ingredients in TRANSDERM SCÖP?

Active ingredient: scopolamine

Inactive ingredients: light mineral oil, polyisobutylene, polypropylene and aluminized polyester film

Marketed by: **Baxter Healthcare Corporation,**
Deerfield, IL 60015 USA

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For more information, go to www.transdermscop.com or call Baxter Healthcare Corporation at 1 800 ANA DRUG (1-800-262-3784).

INSTRUCTIONS FOR USE
TRANSDERM SCÖP (trans-derm sköp)
(scopolamine transdermal system)

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Information about TRANSDERM SCÖP:

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

To help prevent nausea and vomiting from motion sickness:

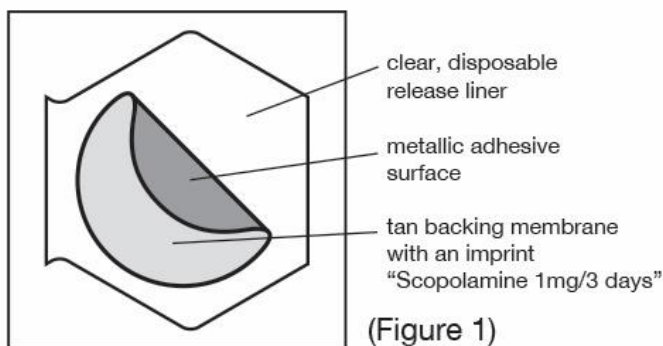
- Apply one TRANSDERM SCÖP to your skin on a hairless area behind one ear at least 4 hours before the activity to prevent nausea and vomiting.
- If the treatment is needed for longer than 3 days, remove TRANSDERM SCÖP from the hairless area behind your ear. Get a new TRANSDERM SCÖP and place it on the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

To help prevent nausea and vomiting after surgery:

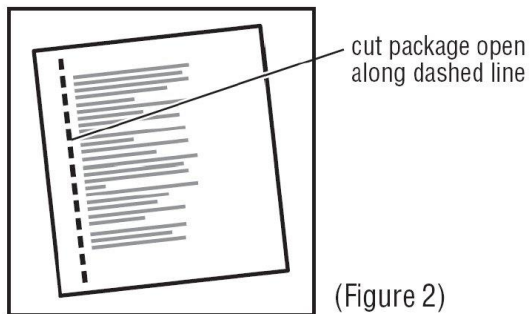
- Follow your doctor’s instructions about when to apply TRANSDERM SCÖP before your scheduled surgery.
- TRANSDERM SCÖP should be left in place for 24 hours after surgery. After 24 hours, TRANSDERM SCÖP should be removed and thrown away.

How to use TRANSDERM SCÖP:

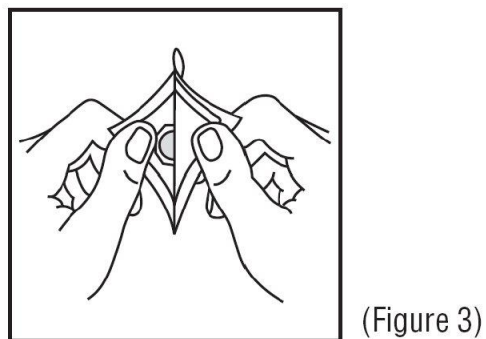
Inside the TRANSDERM SCÖP package, you will find one TRANSDERM SCÖP. An imprinted, tan backing membrane with a metallic (silver) sticky surface is adhered to a clear, disposable release liner (See Figure 1).



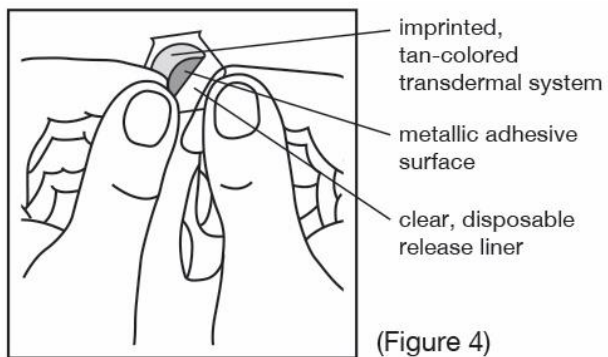
1. Select a hairless area of skin behind one of your ears. Avoid areas on your skin that may have cuts, pain or tenderness. Wipe the area of your skin with a clean, dry tissue.
2. Cut along the dashed line on the TRANSDERM SCÖP package to open (See Figure 2).



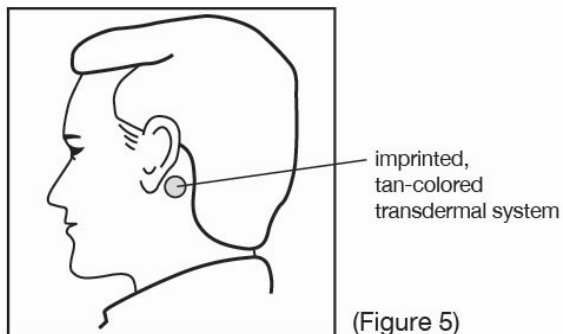
3. Remove the clear plastic backing from the tan-colored round TRANSDERM SCÖP (See Figure 3).



4. **Do not** touch the metallic adhesive (sticky) surface on TRANSDERM SCÖP with your hands (See Figure 4).



5. Apply the metallic adhesive surface of TRANSDERM SCÖP firmly to the dry area of skin behind your ear. The imprinted, tan colored side of the transdermal system should be facing up and showing (See Figure 5). After placement of TRANSDERM SCÖP, avoid touching or applying pressure to the transdermal system while it is being worn because applying pressure may cause scopolamine to ooze out at the edge. Wash your hands with soap and water right away after applying TRANSDERM SCÖP, so that any medicine from TRANSDERM SCÖP that gets on your hands will not get into your eyes.



How to remove TRANSDERM SCÖP:

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

How should I store TRANSDERM SCÖP?

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

Keep TRANSDERM SCÖP and all medicines out of reach of children.

The Patient Information and Instructions for Use have been approved by the U.S. Food and Drug Administration

Revised: March 2024

07-19-00-4945