

PATIENT INFORMATION

Transderm Scöp®,
pronounced
tran(t)s-derm sköp
(scopolamine)
transdermal system patch



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®?

The Transderm Scöp® patch is a prescription medicine used for adults to:

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

It is not known if Transderm Scöp® is safe or effective in children.

Who should not use Transderm Scöp®?

Do not use Transderm Scöp® if you:

- have an eye problem called angle closure glaucoma
- if you are allergic to any of the ingredients in Transderm Scöp® or other medicines called belladonna alkaloids. See the end of this 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 if you:

- are scheduled to have a gastric secretion test
- have glaucoma (increased pressure in the eye)
- have liver or kidney problems
- have problems with your stomach or intestines
- have trouble urinating
- have a history of seizures or psychosis
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if Transderm Scöp® can harm your unborn baby.
- are breast-feeding or plan to breast-feed. Transderm Scöp® 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 Transderm Scöp®.

Tell your doctor about all the medicines you take, including prescription and non-prescription 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 or tranquilizer (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®?

Use Transderm Scöp® exactly as your doctor tells you to use it.

Transderm Scöp® is a tan-colored, circle shaped patch with an imprint of "Scopolamine" 1 mg/3 days®.

Wear only one patch at any time.

Do not cut the patch.

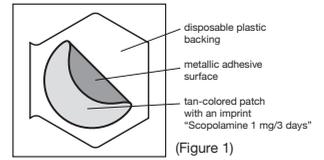
To help prevent nausea and vomiting from motion sickness:

- Apply one Transderm Scöp® patch 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 the patch from the hairless area behind your ear. Get a new Transderm Scöp® patch and place it on the hairless area behind your other ear.

To help prevent nausea and vomiting after surgery:

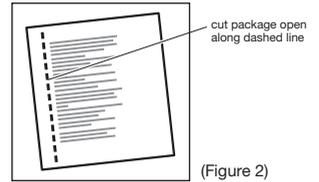
- Follow your doctor's instructions about when to apply Transderm Scöp® before your scheduled surgery.
- The Transderm Scöp® patch should be left in place for 24 hours after surgery. After 24 hours the patch should be removed and thrown away.

Apply Transderm Scöp® as follows: Inside the Transderm Scöp® package, you will find one Transderm Scöp® patch. An imprinted tan colored patch with a metallic (silver) sticky surface is adhered to a clear disposable backing (See Figure 1).

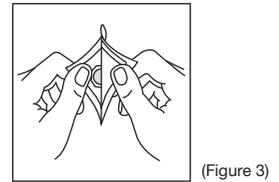


1. Select a hairless area of skin behind one of your ears. Avoid areas on your skin that may have cuts, pain or tenderness. Wipe the area of your skin with a clean, dry tissue.

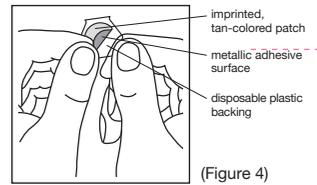
2. Cut along dotted line on the Transderm Scöp® package to open (See Figure 2).



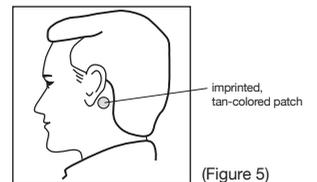
3. Remove the clear plastic backing from the imprinted, tan-colored round patch (See Figure 3).



4. Avoid touching the metallic adhesive (sticky) surface on the patch with your hands (See Figure 4).



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



Sandoz Inc. 100 College Road West Princeton, NJ 08540 SANDOZ	Description: TRANSDERM SCOP — US — Patient Information (PPI) Page 1 of 2	RA Approval #1:
	Component #: 11422 Replaces: 46114067	RA Approval #2 (if applicable):
	Rev. Date: December 2016	RA Approval (CMC):
	Dimensions: 7.44" W x 12" H Drawing #: XXXXXXXX	QA Approval (if applicable):
	Font Family: Myriad Pro Size: 10 pt. Print Colors: ■ BLACK Tech. Colors: ■ Cutting (does not print) ■ CREASING (does not print)	

After removing the patch, be sure to wash your hands and the area behind your ear thoroughly with soap and water. Note that the used patch will still contain some of the active ingredient after use. To avoid accidental contact or ingestion by children or pets, fold the used patch in half with the sticky side together. Dispose in the trash out of the reach of children and pets.

If you use too much Transderm Scöp®, call your doctor or local poison control center, 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® patch 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 the Transderm Scöp® patch may fall off. If the patch 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 the patch and call a doctor right away if you get pain and reddening of your eyes with an increase in the size of your pupil (the small dark circle in the eye).
- **temporary increase in the size of your pupil and blurry vision,** especially if Transderm Scöp® comes in contact with your eyes
- **difficulties in urinating**
- **difficulties in food passing from the stomach to the small intestines, which may cause abdominal pain, nausea or vomiting.**
- **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)

• **skin burns at the site of the patch.** 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
- drowsiness
- disorientation (confusion)
- blurred vision
- pharyngitis
- memory trouble
- dizziness
- restlessness
- agitation
- problems urinating
- skin rashes or redness, application site burning
- dry itchy, or reddened whites of the eyes, and eye pain

Symptoms when removing Transderm Scöp®. Some people may have certain symptoms 24

hours or more after removing Transderm Scöp®. These symptoms may include:

- dizziness
- nausea
- vomiting
- headache
- problems with balance and walking
- decrease in blood pressure
- muscle weakness
- decrease in heart rate

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®. For more information, ask your doctor or pharmacist.

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

How should I store Transderm Scöp®?

- Store Transderm Scöp® at room temperature between 68°-77°F (20°-25°C) until you are ready to use it.
- **Keep Transderm Scöp® and all medicines out of reach of children.**

General Information about 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.

This patient information leaflet summarizes the most important information about Transderm Scöp®. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Transderm Scöp® that is written for the health professionals.

For more information, go to www.transdermscop.com or call Sandoz Inc. at 1-800-525-8747.

What are the ingredients in the Transderm Scöp® patch?

Active ingredient: Scopolamine
Inactive ingredients: light mineral oil polyisobutylene and aluminized polyester film

Manufactured by ALZA Corporation
 Vacaville, CA 95688 for
 Sandoz Inc., Princeton, NJ 08540

Rev.: December 2016

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