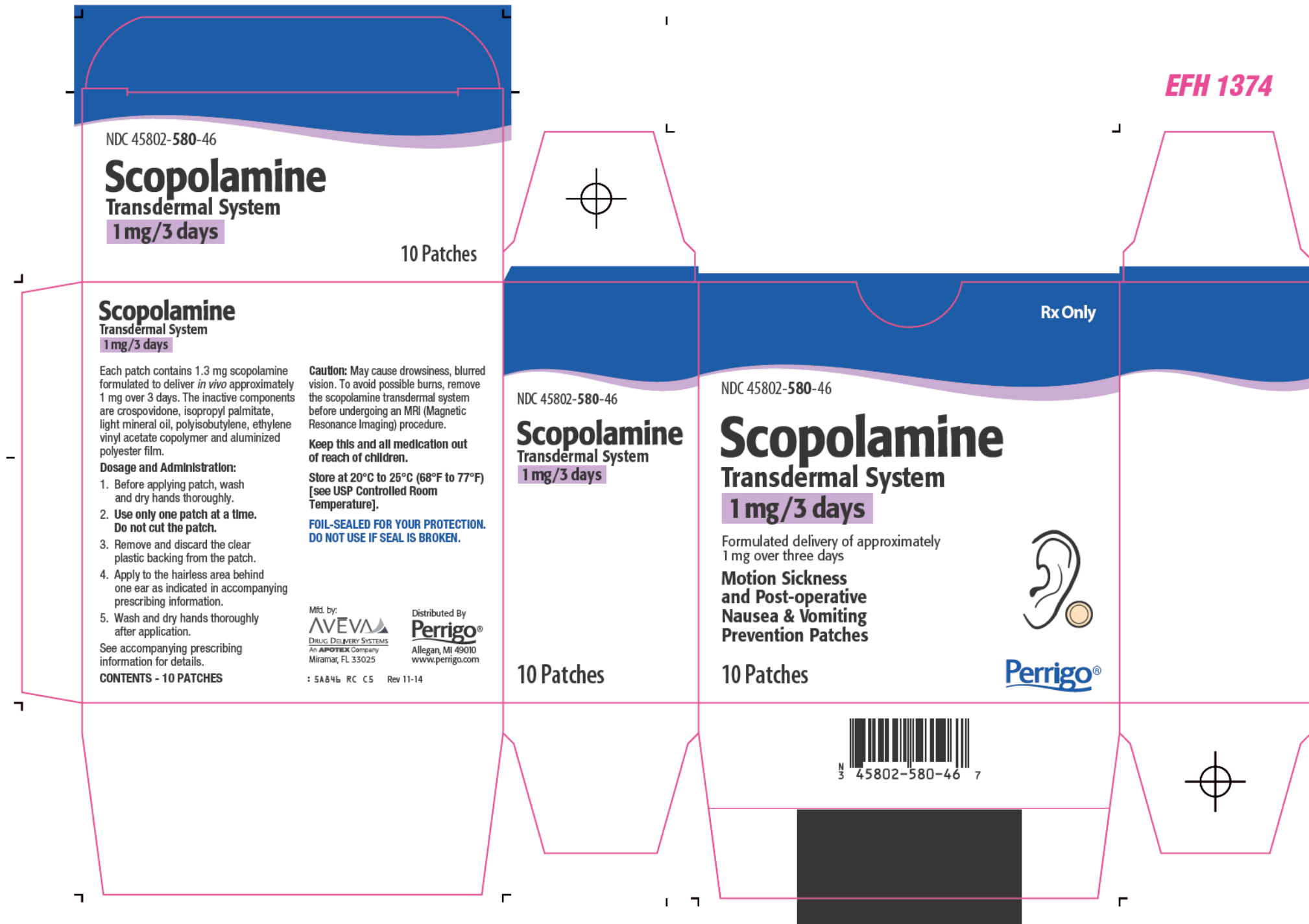


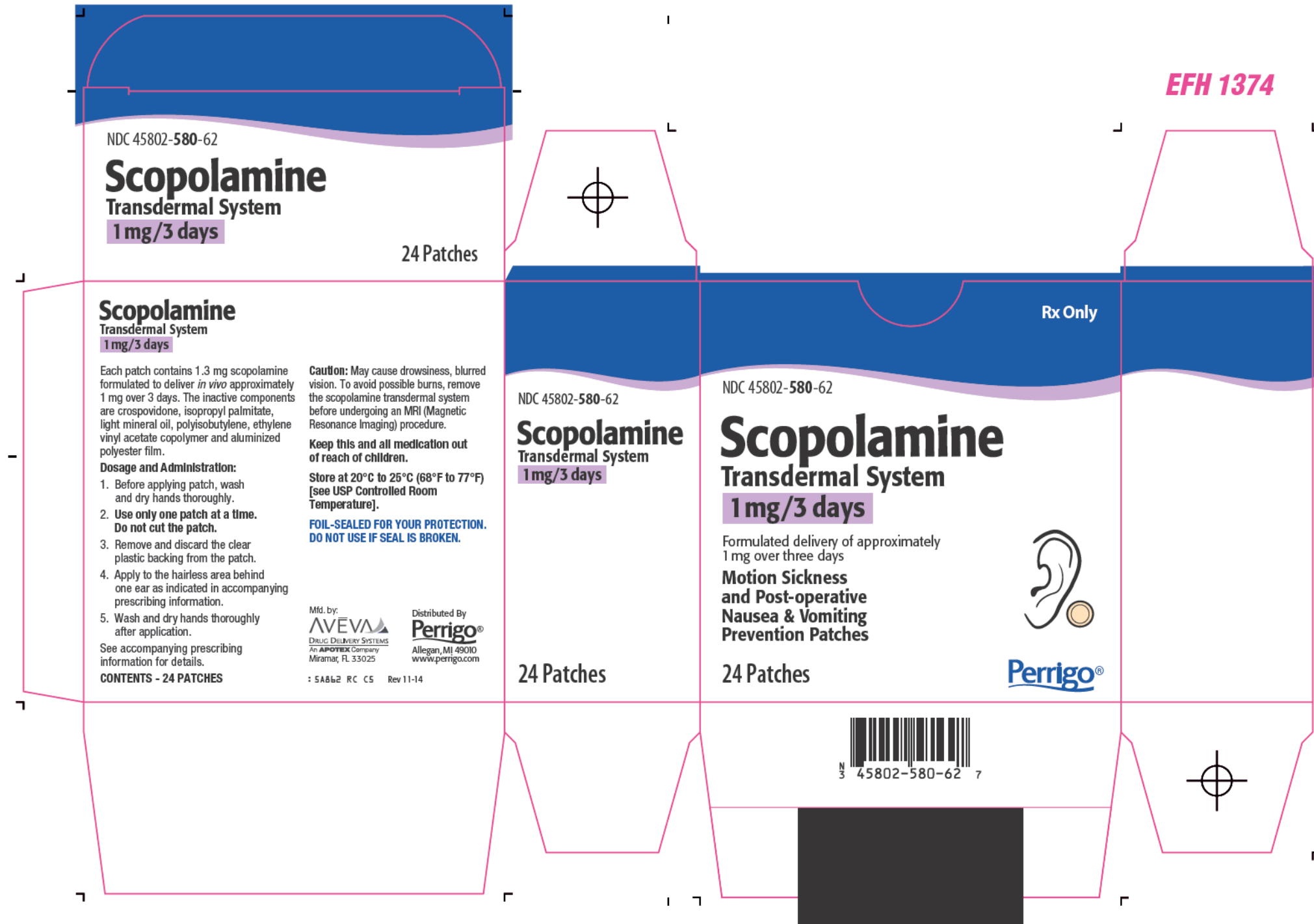
Final Printed Labeling
Carton - 4 ct



Final Printed Labeling
Carton - 10 ct

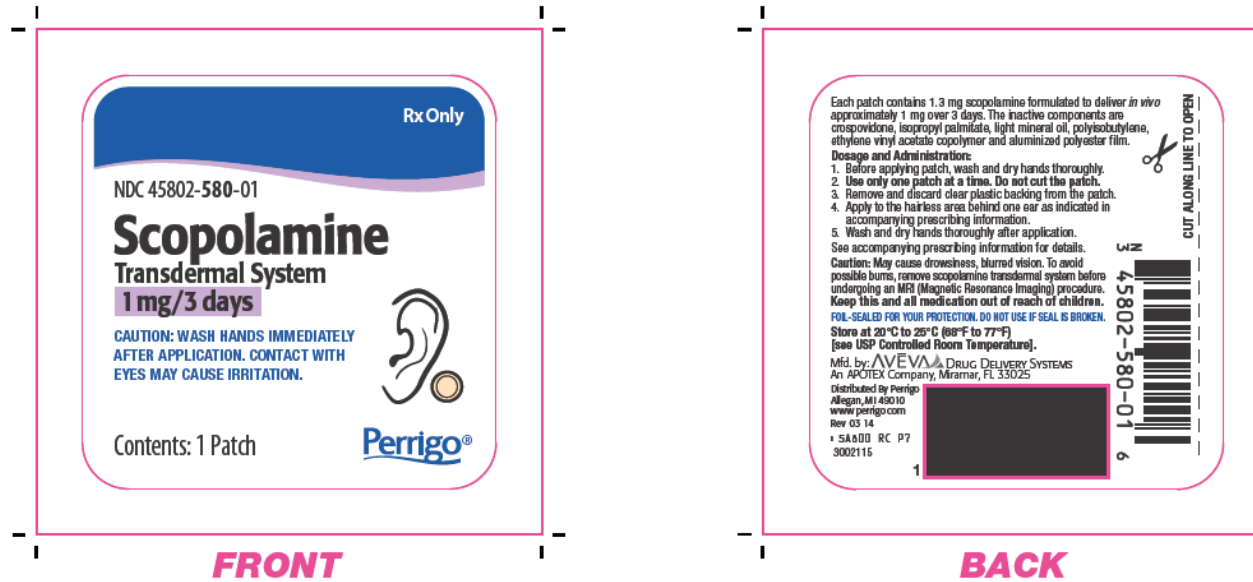


Final Printed Labeling
Carton - 24 ct



Final Printed Labeling
Patch

FPC 247



12-02-14

Final Printed Labeling Physician Insert

HIGHLIGHTS OF PRESCRIBING INFORMATION These highlights do not include all the information needed to use scopolamine transdermal system safely and effectively. See full prescribing information for scopolamine transdermal system.

Scopolamine Transdermal System 1 mg/3 days Initial U.S. Approval: 1979

INDICATIONS AND USAGE

Scopolamine transdermal system is an anticholinergic agent indicated in adults for the prevention of nausea and vomiting associated with:

- Motion Sickness (1.1)
• Post Operative Nausea and Vomiting (PONV) (1.2)

DOSAGE AND ADMINISTRATION

DO NOT cut the patch. Apply ONE patch in the postauricular area to prevent:

- Apply 4 hrs before antiemetic effect is required for use up to 3 days (2.1)
• For use longer than 3 days, remove current patch and place new patch behind other ear (2.2)

- Apply evening before scheduled surgery (2.1)
• For cesarean section, apply 1 hour prior to surgery (2.1)
• Discard 24 hrs after surgery (2.2)

DOSAGE FORMS AND STRENGTHS

Continuous release, circular, flat, tan colored patch (1.3 mg scopolamine) (3)

CONTRAINDICATIONS

- Patients with angle closure glaucoma (4, 6, 2)
• Persons who are hypersensitive to scopolamine or to other belladonna alkaloids (4, 7)

WARNINGS AND PRECAUTIONS

- Use with caution in patients with open angle glaucoma (5.1)
• Stop use if patient experiences symptoms of acute closure glaucoma (5.1, 6.2)
• Can cause temporary dilation and blurred vision if scopolamine contacts the eyes (5.2, 6, 16)
• Use caution in patients with a history of seizures or psychosis (5.4)

FULL PRESCRIBING INFORMATION: CONTENTS*

- 1 INDICATIONS AND USAGE
1.1 Motion Sickness
1.2 Post Operative Nausea and Vomiting (PONV)
2 DOSAGE AND ADMINISTRATION
2.1 Initiation of Therapy
2.2 Continuation of Therapy
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Open Angle Glaucoma
5.2 Temporary Dilation of the Pupil
5.3 Preexisting Gastrointestinal or Urinary Bladder Obstructions
5.4 History of Seizures or Psychosis
5.5 Idiosyncratic Reactions
5.6 Specific Populations
5.7 Safety Hazards
5.8 MRI Skin Burns
6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
6.2 Postmarketing Experience
6.3 Drug Withdrawal/Post-Removal Symptoms
7 DRUG INTERACTIONS
7.1 Laboratory Test Interactions

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
1.1 Motion Sickness
Scopolamine transdermal system is indicated in adults for prevention of nausea and vomiting associated with motion sickness. [see Clinical Studies (14.1)]
1.2 Post Operative Nausea and Vomiting (PONV)
Scopolamine transdermal system is indicated in adults for prevention of nausea and vomiting associated with recovery from anesthesia and/or opiate analgesia and surgery. [see Clinical Studies (14.2)]
2 DOSAGE AND ADMINISTRATION
Each scopolamine transdermal system is formulated to deliver in-vivo approximately 1 mg of scopolamine over 3 days. Only one patch should be worn at any time. Do not cut the patch.
The patch should be applied only to the skin in the postauricular (hairless area behind one ear) area.
Handling
After the patch is applied on the dry skin behind the ear, the hands should be washed thoroughly with soap and water and dried. Upon removal, the patch should be discarded. To prevent any traces of scopolamine from coming into direct contact with the eyes, after administration of the patch, the hands and the application site should be washed thoroughly with soap and water and dried. [see How Supplied/Storage and Handling (16) and Patient Counseling Information (17)]
2.1 Initiation of Therapy
Motion Sickness
• To prevent the nausea and vomiting associated with motion sickness, one scopolamine transdermal system (formulated to deliver approximately 1 mg of scopolamine over 3 days) should be applied to the hairless area behind one ear at least 4 hours before the antiemetic effect is required.
Post Operative Nausea and Vomiting
• To prevent post operative nausea and vomiting, one scopolamine transdermal system should be applied the evening before scheduled surgery, except for cesarean section.

- Use with caution in patients with pyloric obstruction, urinary bladder neck obstruction, or patients suspected of having intestinal obstruction (5.3)
• Stop use if patient has difficulty urinating (5.3, 6)
• Idiosyncratic reactions, such as confusion, agitation, speech disorder, hallucinations, paranoia and delusions, may occur with therapeutic doses of scopolamine (5.5, 6.2)
• A safe and effective dose has not been established in the pediatric population (5.6, 8.4)
• Use with caution in the elderly because of the increased likelihood of CNS effects, such as hallucinations, confusion and dizziness (5.6, 8.5)
• Should be used with caution in patients with impaired renal or hepatic function because of the increased likelihood of CNS effects (5.6, 8.5, 8.6)
• May cause drowsiness or disorienting effects, therefore patients should be cautioned against engaging in activities that require mental alertness, such as driving a motor vehicle or operating dangerous machinery (5.7)
• Skin burns have been reported in patients undergoing MRI testing (5.8)

ADVERSE REACTIONS

Most common adverse reactions during motion sickness clinical trials are dry mouth, drowsiness and blurred vision. (6.1)
Most common adverse reactions during PONV trials (≥ than 3%) are dry mouth, dizziness, somnolence, urinary retention, agitation, visual impairment, confusion, mydriasis and pharyngitis. (6.1)
To report SUSPECTED ADVERSE REACTIONS, contact Perrigo at 1-866-634-9120 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Absorption of oral medications may be decreased (7)
• Use with care while taking sedatives, tranquilizers or alcohol (7)
• Potential interactions with drugs having anticholinergic properties (7)
• Scopolamine interferes with the gastric secretion test (7.1)

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on animal data, may cause fetal harm (8.1)
• Nursing mothers: Caution should be exercised when administered to a nursing woman (8.3)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling. Revised: November 2014

8 USE IN SPECIFIC POPULATIONS

- 8.1 Pregnancy
8.2 Labor and Delivery
8.3 Nursing Mothers
8.4 Pediatric Use
8.5 Geriatric Use
8.6 Renal or Hepatic Impairment

9 DRUG ABUSE AND DEPENDENCE

- 9.1 Controlled Substance
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10 OVERDOSAGE

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13 NONCLINICAL TOXICOLOGY

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- 14.1 Motion Sickness
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17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

• For cesarean section surgery, to minimize exposure of the newborn baby to the drug, apply the patch one hour prior to cesarean section.
2.2 Continuation of Therapy
Should the patch become displaced, it should be discarded, and a fresh one placed on the hairless area behind the other ear.
Motion Sickness
If therapy is required for longer than 3 days, the first patch should be removed and a fresh one placed on the hairless area behind the other ear.
For peroperative use, the patch should be kept in place for 24 hours following surgery at which time it should be removed and discarded.
3 DOSAGE FORMS AND STRENGTHS
The scopolamine transdermal system is a tan-colored circular flat patch which contains 1.3 mg of scopolamine base and is formulated to deliver in-vivo approximately 1 mg of scopolamine over 3 days.
4 CONTRAINDICATIONS
Scopolamine transdermal system is contraindicated in the following populations:
• Patients with angle closure glaucoma. [see Adverse Reactions (6)]
• Persons who are hypersensitive to the drug scopolamine or other belladonna alkaloids or to any ingredient or component in the formulation or delivery system. [see Drug Interactions (7) and Description (11)]
5 WARNINGS AND PRECAUTIONS
5.1 Open Angle Glaucoma
Patients currently being treated for Open Angle Glaucoma
Glaucoma therapy in patients with open angle glaucoma should be monitored and
• Patients with angle closure glaucoma. [see Adverse Reactions (6)]
• Persons who are hypersensitive to the drug scopolamine or other belladonna alkaloids or to any ingredient or component in the formulation or delivery system. [see Drug Interactions (7) and Description (11)]
5.2 Temporary Dilation of the Pupil
Glaucoma therapy in patients with open angle glaucoma should be monitored and
• Patients with angle closure glaucoma. [see Adverse Reactions (6)]
• Persons who are hypersensitive to the drug scopolamine or other belladonna alkaloids or to any ingredient or component in the formulation or delivery system. [see Drug Interactions (7) and Description (11)]
5.3 Preexisting Gastrointestinal or Urinary Bladder Obstructions
Glaucoma therapy in patients with open angle glaucoma should be monitored and
• Patients with angle closure glaucoma. [see Adverse Reactions (6)]
• Persons who are hypersensitive to the drug scopolamine or other belladonna alkaloids or to any ingredient or component in the formulation or delivery system. [see Drug Interactions (7) and Description (11)]
5.4 History of Seizures or Psychosis
Glaucoma therapy in patients with open angle glaucoma should be monitored and
• Patients with angle closure glaucoma. [see Adverse Reactions (6)]
• Persons who are hypersensitive to the drug scopolamine or other belladonna alkaloids or to any ingredient or component in the formulation or delivery system. [see Drug Interactions (7) and Description (11)]
5.5 Idiosyncratic Reactions
Glaucoma therapy in patients with open angle glaucoma should be monitored and
• Patients with angle closure glaucoma. [see Adverse Reactions (6)]
• Persons who are hypersensitive to the drug scopolamine or other belladonna alkaloids or to any ingredient or component in the formulation or delivery system. [see Drug Interactions (7) and Description (11)]
5.6 Specific Populations
Glaucoma therapy in patients with open angle glaucoma should be monitored and
• Patients with angle closure glaucoma. [see Adverse Reactions (6)]
• Persons who are hypersensitive to the drug scopolamine or other belladonna alkaloids or to any ingredient or component in the formulation or delivery system. [see Drug Interactions (7) and Description (11)]
5.7 Safety Hazards
Glaucoma therapy in patients with open angle glaucoma should be monitored and
• Patients with angle closure glaucoma. [see Adverse Reactions (6)]
• Persons who are hypersensitive to the drug scopolamine or other belladonna alkaloids or to any ingredient or component in the formulation or delivery system. [see Drug Interactions (7) and Description (11)]
5.8 MRI Skin Burns
Glaucoma therapy in patients with open angle glaucoma should be monitored and
• Patients with angle closure glaucoma. [see Adverse Reactions (6)]
• Persons who are hypersensitive to the drug scopolamine or other belladonna alkaloids or to any ingredient or component in the formulation or delivery system. [see Drug Interactions (7) and Description (11)]

Patients should be strongly advised to wash their hands thoroughly with soap and water immediately after handling the patch. [see Adverse Reactions (6)] In addition, it is important that used patches be disposed of properly to avoid contact with children or pets. [see How Supplied/Storage and Handling (16)]

5.3 Preexisting Gastrointestinal or Urinary Bladder Obstructions

Scopolamine transdermal system should be used with caution in patients with pyloric obstruction or urinary bladder neck obstruction. Caution should be exercised when administering an antiemetic or anticholinergic drug, including scopolamine transdermal system, to patients suspected of having intestinal obstruction.

5.5 Idiosyncratic Reactions

Idiosyncratic reactions may occur with ordinary therapeutic doses of scopolamine. Some symptoms may be related to adaptation from a motion environment. These symptoms can be severe and may require medical intervention. Some symptoms may be related to adaptation from a motion environment. These symptoms can be severe and may require medical intervention.

5.6 Specific Populations

Pediatric: A safe and effective dose has not been established in the pediatric population [see Use in Specific Populations (8.4)]. Children are particularly susceptible to the side effects of belladonna alkaloids, including mydriasis, hallucinations, amblyopia, and drug withdrawal syndrome. Neurologic and psychiatric adverse reactions, such as hallucinations, amblyopia and mydriasis have also been reported when one half or one quarter of a patch has been applied.

Elderly

Scopolamine transdermal system should be used with caution in the elderly because of the increased likelihood of CNS effects, such as hallucinations, confusion, dizziness and drug withdrawal syndrome. Clinical trials of scopolamine transdermal system did not include sufficient number of subjects aged 65 years and older to determine if they respond differently from younger subjects. [see Use in Specific Populations (8.5)]

Renal and Hepatic Impairment

Scopolamine transdermal system should be used with caution in individuals with impaired renal or hepatic functions because of the increased likelihood of CNS effects. Scopolamine transdermal system has not been studied in these populations. [see Use in Specific Populations (8.6)]

5.7 Safety Hazards

Drowsiness: Since drowsiness, disorientation, and confusion may occur with the use of scopolamine, patients should be warned of the possibility and cautioned against engaging in activities that require mental alertness, such as driving a motor vehicle or operating dangerous machinery.

5.8 MRI Skin Burns

Skin burns have been reported at the patch site in several patients wearing an aluminum transdermal system during a Magnetic Resonance Imaging scan (MRI). Because scopolamine transdermal system contains aluminum, it is recommended to remove the system before undergoing an MRI.

6 ADVERSE REACTIONS

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

6.2 Postmarketing Experience

The following adverse drug reactions, further to those reported from clinical trials, have been identified during postapproval use of scopolamine transdermal system. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or to confirm a definite causal relationship.

6.3 Postmarketing Experience

The following adverse drug reactions, further to those reported from clinical trials, have been identified during postapproval use of scopolamine transdermal system. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or to confirm a definite causal relationship.

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6.7 Postmarketing Experience

The following adverse drug reactions, further to those reported from clinical trials, have been identified during postapproval use of scopolamine transdermal system. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or to confirm a definite causal relationship.

General disorders and administration site conditions: application site burning. Eye disorders: dry eyes, eye pruritus, acute closure glaucoma, amblyopia, eyelid irritation. Skin and subcutaneous tissue disorders: rash generalized, skin irritation, erythema. Renal and urinary disorders: dysuria. Rest and Labyrinth Disorders: vertigo.

6.3 Drug Withdrawal/Post-Removal Symptoms

Symptoms such as dizziness, nausea, vomiting, abdominal cramps, sweating, headache, mental confusion, muscle weakness, bradycardia and hypotension may occur following abrupt discontinuation of anticholinergic drugs such as scopolamine transdermal system. Similar symptoms, including disturbances of equilibrium, have been reported in some patients following discontinuation of use of the scopolamine transdermal system. These symptoms usually do not appear until 24 hours or more after the patch has been removed. These symptoms can be severe and may require medical intervention. Some symptoms may be related to adaptation from a motion environment. These symptoms can be severe and may require medical intervention.

7 DRUG INTERACTIONS

The absorption of oral medications may be decreased during the concurrent use of scopolamine because of decreased gastric motility and delayed gastric emptying. [see Warnings and Precautions (5.3)]

7.1 Laboratory Test Interactions

Scopolamine may interfere with the gastric secretion test.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C Based on data from one prospective study of scopolamine transdermal system in cesarean delivery, the rate of newborn adverse events in both the scopolamine transdermal system and placebo groups were the same. The rates were 10.5% (12 events in 114 newborns) in both treatment groups. None of these events were considered life threatening or drug related. Jaundice was the only adverse event occurring more frequently with scopolamine transdermal system than placebo: 9 events (7.9%) versus 2 events (1.8%) (p=0.031). Jaundice, a common occurrence in newborns, resolved with ultraviolet light and did not prolong the hospital stay.

8.2 Labor and Delivery

During a clinical study among women undergoing cesarean section treated with scopolamine transdermal system in conjunction with epidural anesthesia and opiate analgesia, no evidence of CNS depression was found in newborns. [see Clinical Studies (14.2)] Scopolamine administered parenterally to rats and rabbits at doses higher than the dose delivered by scopolamine transdermal system did not affect uterine contractions or increase the duration of labor. Scopolamine does cross the placenta.

8.3 Nursing Mothers

Scopolamine is excreted in human milk. Caution should be exercised when scopolamine transdermal system is administered to a nursing woman.

8.4 Pediatric Use

A safe and effective dose has not been established in the pediatric population. [see Warnings and Precautions (5.6)]

8.5 Geriatric Use

Scopolamine transdermal system should be used with caution in the elderly because of the increased likelihood of CNS effects, such as hallucinations, confusion and dizziness. Clinical trials of scopolamine transdermal system did not include sufficient number of subjects aged 65 years and older to determine if they respond differently from younger subjects. [see Warnings and Precautions (5.6)]

8.6 Renal or Hepatic Impairment

Scopolamine transdermal system should be used with caution in individuals with impaired renal or hepatic functions because of the increased likelihood of CNS effects. [see Warnings and Precautions (5.6)]

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance Class

Scopolamine is not a controlled substance.

9.2 Abuse

Scopolamine is an antagonist of muscarinic receptors in the cholinergic system. Drugs in this class are not known to have significant abuse potential in humans.

9.3 Dependence

Abrupt termination of scopolamine transdermal system may result in withdrawal symptoms such as dizziness, nausea, vomiting, abdominal cramps, sweating, headache, mental confusion, muscle weakness, bradycardia and hypotension. [see Adverse Reactions (6.3) and Overdosage (10)]. These withdrawal symptoms indicate that anticholinergic drugs, like scopolamine may produce physical dependence. These symptoms can be severe and may require medical intervention.

10 OVERDOSAGE

Because strategies for the management of drug overdose continually evolve, it is strongly recommended that a poison control center be contacted to obtain up-to-date information regarding the management of scopolamine transdermal system overdose. The prescriber should be mindful that antidotes used routinely in the past may no longer be considered optimal treatment.

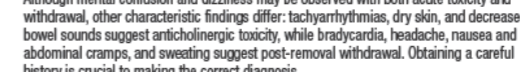
11 DESCRIPTION

The scopolamine transdermal system is a circular flat patch designed for continuous release of scopolamine following application to an area of intact skin on the head, behind the ear. Each system contains 1.3 mg of scopolamine base. Scopolamine is a (1S)-8-methyl-8-azabicyclo[3.2.1]octane-8-carboxylic acid (3S,1R)-[3,3,1,0]non-7-yl ester. The empirical formula is C₂₁H₂₇NO₂ and its structural formula is:

In cases of toxicity remove the patch. Serious symptomatic cases of overdose involving multiple patch applications and/or ingestion may be managed by initially ensuring the patient has an adequate airway, and supporting respiration and circulation. This should be rapidly followed by removal of all patches from the skin and the mouth. If there is evidence of patch ingestion, gastric lavage, endoscopic removal of swallowed patches, or administration of activated charcoal should be considered, as indicated by the clinical situation. In any case where there is serious overdose or signs of evolving acute toxicity, continuous monitoring of vital signs and ECG, establishment of intravenous access, and administration of oxygen are all recommended.

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Scopolamine is a white to almost white, crystalline powder that has a molecular weight of 350.35 and a pKa of 5.5-7.41. The scopolamine transdermal system is a film 0.2 mm thick and 2.5 cm², with four layers. Proceeding from the visible surface towards the surface attached to the skin, these layers are: (1) a backing layer of tan-colored, aluminum, polyethylene glycol, (2) a drug reservoir of croscopolone, croscopolol palmitate, light mineral oil, polyisobutylene, and polyethylene glycol, (3) an ethylene vinyl acetate copolymer membrane that controls the rate of delivery of scopolamine from the system to the skin surface, and (4) an adhesive formulation of croscopolone, croscopolol palmitate, light mineral oil, polyisobutylene, and polyethylene glycol. A protective peel strip of aluminum polyester, which covers the adhesive layer, is removed before the system is used. The inactive components, croscopolone (3.63 mg), croscopolol palmitate (1.81 mg), light mineral oil (11.42 mg) and polyisobutylene (16.83 mg), are not released from the system.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Scopolamine is a belladonna alkaloid, is an anticholinergic agent. Scopolamine acts: (i) as a competitive inhibitor of postganglionic muscarinic receptor sites of the parasympathetic nervous system, and (ii) on smooth muscles that respond to acetylcholine but lack cholinergic innervation. It has been suggested that scopolamine acts in the central nervous system (CNS) by blocking cholinergic transmission from the vestibular nuclei to higher centers in the CNS and from the reticular formation to the vomiting center. Scopolamine can inhibit the secretion of saliva and sweat, decrease gastrointestinal secretions and motility, cause drowsiness, dilate the pupils, increase heart rate, and depress motor function.

12.2 Pharmacokinetics

The pharmacokinetics of scopolamine delivered via the system are due to the characteristics of both the drug and dosage form. The system is formulated to deliver in-vivo approximately 1 mg of scopolamine at an approximately constant rate to the systemic circulation over 3 days. Upon application to the postauricular skin, an initial priming dose of scopolamine is released from the adhesive layer to saturate skin-binding sites. The subsequent delivery of scopolamine to the blood is determined by the rate controlling membrane and is designed to produce stable plasma levels in a therapeutic range. Following removal of the used system, there is some degree of continued systemic absorption of scopolamine bound in the skin layers.

12.3 Distribution

Scopolamine is well absorbed percutaneously. Following application to the skin behind the ear, circulating plasma levels are detected within 4 hours with peak levels being obtained, on average, within 24 hours. The average plasma concentration produced is 87 pg/mL (0.28 nM) for free scopolamine and 354 pg/mL for total scopolamine (free + conjugated).

12.4 Metabolism and Excretion

The exact elimination pattern of scopolamine has not been determined. Following the exact elimination pattern of scopolamine decline in a log linear fashion with observed half-life of 9.5 hours. Less than 10% of the total dose is excreted in the urine as the parent drug and metabolites over 168 hours. Scopolamine is extensively metabolized and conjugated with less than 5% of the total dose appearing unchanged in the urine. The enzymes responsible for metabolizing scopolamine are unknown.

12.5 In Vitro Studies

In an in vitro study using human liver microsomes which evaluated the inhibition of CYP1A2, 2C8, 2C9, 2C19, 2D6 and 3A4, scopolamine did not inhibit these cytochrome group (plasma level approximately 500 times the level achieved in humans using a transdermal system). However, fertility studies in male animals were not performed.

12.6 In Vitro Studies

In an in vitro study using human liver microsomes which evaluated the inhibition of CYP1A2, 2C8, 2C9, 2C19, 2D6 and 3A4, scopolamine did not inhibit these cytochrome group (plasma level approximately 500 times the level achieved in humans using a transdermal system). However, fertility studies in male animals were not performed.

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In an in vitro study using human liver microsomes which evaluated the inhibition of CYP1A2, 2C8, 2C9, 2C19, 2D6 and 3A4, scopolamine did not inhibit these cytochrome group (plasma level approximately 500 times the level achieved in humans using a transdermal system). However, fertility studies in male animals were not performed.

14 CLINICAL STUDIES

14.1 Motion Sickness

In 193 adult subjects of different racial origins who participated in clinical efficacy studies at sea or in a controlled motion environment, there was a 75% reduction in the incidence of motion-induced nausea and vomiting.

Final Printed Labeling
Patient Insert

FDA-Approved Patient Labeling

PATIENT INFORMATION

Scopolamine transdermal system 1 mg/3 days

Read this Patient Information 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?

The scopolamine transdermal system 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 scopolamine transdermal system is safe or effective in children.

Who should not use scopolamine transdermal system?

Do not use scopolamine transdermal system if you:

- have an eye problem called angle closure glaucoma
- if you are allergic to any of the ingredients in scopolamine transdermal system or other medicines called belladonna alkaloids. 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 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 scopolamine transdermal system can harm your unborn baby.
- are breast-feeding or plan to breast-feed. 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 non-prescription 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:

- 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 scopolamine transdermal system?

Use scopolamine transdermal system exactly as your doctor tells you to use it.

Scopolamine transdermal system is a tan-colored circle shaped patch.

Wear only one patch at any time.

Do not cut the patch.

To help prevent nausea and vomiting from motion sickness:

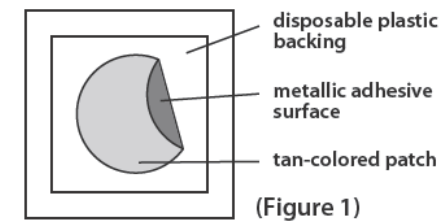
- Apply one scopolamine transdermal system to your skin on a hairless area behind one ear at least 4 hours before the activity to prevent nausea and vomiting.
- If the treatment is needed for longer than 3 days, remove the patch from the hairless area behind your ear. Get a new scopolamine transdermal 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.
- The scopolamine transdermal system should be left in place for 24 hours after surgery. After 24 hours the patch should be removed and thrown away.

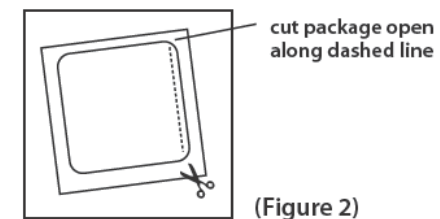
Apply scopolamine transdermal system as follows:

Inside the scopolamine transdermal system package, you will find one scopolamine transdermal system. A tan colored patch with a metallic (silver) sticky surface is adhered to a clear disposable backing (See Figure 1).



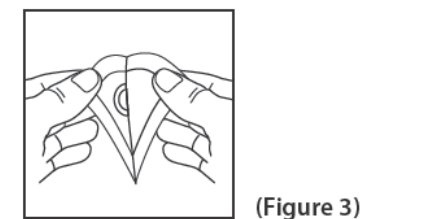
(Figure 1)

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 scopolamine transdermal system package to open (See Figure 2).



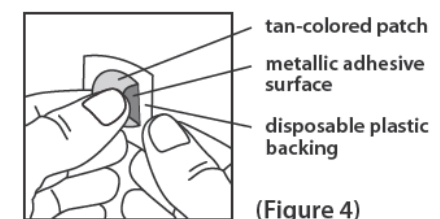
(Figure 2)

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



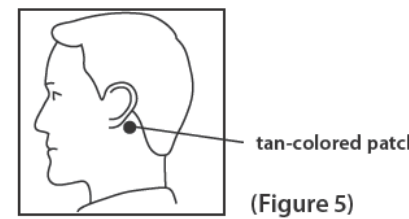
(Figure 3)

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



(Figure 4)

5. Apply the metallic adhesive surface of the patch firmly to the dry area of skin behind your ear. The 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.



(Figure 5)

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 scopolamine transdermal system, call your doctor or local poison control center, 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 the scopolamine transdermal system 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 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 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 scopolamine transdermal system 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 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)

- **skin burns at the site of the patch.** 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
- 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 scopolamine transdermal system. Some people may have certain symptoms 24 hours or more after removing scopolamine transdermal system. 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 scopolamine transdermal system. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. To report SUSPECTED ADVERSE REACTIONS, contact Perrigo Company at 1-866-634-9120, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

How should I store scopolamine transdermal system?

- Store at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].
- **Keep scopolamine transdermal system and all medicines out of reach of children.**

General Information about scopolamine transdermal system

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. 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.

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

For more information, call 1-866-634-9120.

What are the ingredients in the scopolamine transdermal system patch?

Active ingredient: Scopolamine
Inactive ingredients: crospovidone, isopropyl palmitate, light mineral oil, polyisobutylene, ethylene vinyl acetate copolymer and aluminized polyester film

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