

INFORMATION FOR THE CONSUMER

TRANSDERM-V* and HOW TO USE IT

(scopolamine)

Transdermal Therapeutic System

INTRODUCTION

This leaflet is intended to help you understand what TRANSDERM-V* is and how it helps to prevent nausea and vomiting associated with motion sickness in adults. Please read it carefully. If you want to know more or have any questions, please ask your doctor or pharmacist.

HOW TRANSDERM-V* PREVENTS MOTION SICKNESS

In some people, motion of ships, airplanes, trains, automobiles, and buses increases activity of the nerve fibers of the inner ear, which are part of the body's balance mechanism. The result is motion sickness, which is characterized by dizziness, nausea, and vomiting. A person suffering from motion sickness may experience one, all, or any combination of these symptoms. Scopolamine is an effective medication for the prevention of nausea and vomiting because it reduces the activity of the nerve fibers in the inner ear and acts on the motion sickness centers in the brain.

TRANSDERM-V* is a small, flexible adhesive disc. When placed behind the ear, it delivers scopolamine to the skin surface from where it is absorbed into the bloodstream over a prolonged period of up to 3 days.

WHAT TRANSDERM-V* CONTAINS

The active substance is scopolamine. TRANSDERM-V* contains 1.5 mg active substance scopolamine per patch.

The other ingredients are light mineral oil/paraffin, light liquid and polyisobutylene.

THINGS TO BE AWARE OF

Although TRANSDERM-V* provides health benefits, certain precautions should be taken before their use and in some situations their use may not be appropriate.

Restrictions on Use

Do not use TRANSDERM-V* if you are allergic (hypersensitive) to scopolamine or have glaucoma.

TRANSDERM-V* should not be used in children. The safety of its use in children has not been determined. Children are particularly sensitive to the effects of scopolamine.

WARNINGS and PRECAUTIONS

Talk to your doctor or pharmacist before using TRANSDERM-V*, if you

- are pregnant or plan to become pregnant while using this medicine
- have any obstructions of the stomach or intestines
- have trouble urinating due to prostate enlargement or any bladder obstruction
- are an elderly patient or have any metabolic, liver, or kidney disease
- have or have had pain in the eyes, blurred vision, or see rainbow-coloured halos around lights (TRANSDERM-V*, should only be used after an eye examination by a doctor).
- have a history of skin allergy or hypersensitivity to any other substance
- have or have had epilepsy or epileptic seizures (increased number of fits have been reported).
- taking any other medicines or remedies, as there are some medicines which may affect how TRANSDERM-V* works

Any of these conditions could make TRANSDERM-V* unsuitable for you.

Breastfeeding women should not take this medicine.

Elderly patients should also consult their doctor before using TRANSDERM-V* as they may be particularly sensitive to the effects of scopolamine.

Avoid drinking alcohol while using TRANSDERM-V*.

Care should be taken after removing the patch, as side-effects may persist for up to 24 hours or longer.

Remove patch before medical scans.

Be careful about driving, performing any activity that requires concentration, or operating any machinery while using the system because the drug might make you feel drowsy, confused, dizzy, or may affect your vision.

Taking other medicines with TRANSDERM-V*.

Tell your doctor or pharmacist if you are taking or have recently taken or want to start taking any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor if you are taking any of the following medicines, because TRANSDERM-V* may interact with them:

- alcohol
- other drugs acting on brain
- antiallergic medicines
- antidepressants
- antiparkinsons and antivirals
- antiarrhythmics
- other travel sickness medicines

POSSIBLE SIDE EFFECTS

Like all medicines, along with its helpful effects, TRANSDERM-V* may cause unwanted side effects. It is wise to be aware of them so that if they do occur you can report them to your doctor.

STOP using TRANSDERM-V* and seek medical help immediately if you have any of the following which may be signs of an allergic reaction:

- difficulty in breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

Some side effects could be serious which are very rare (may affect 1 in every 10,000 people)

- changes in vision with increased pressure in the eye (possible signs of glaucoma)

If you experience this, **tell your doctor straight away.**

Some side effects are very common (may affect more than 1 in 10 people)

- dryness of the mouth
- drowsiness, dizziness
- blurring of (near) vision and enlargement of the pupils (sometimes in one eye only)
- loss of ability to focus on close or far objects (visual accommodation)

Some side effects are common (may affect between 1 and 10 in every 100 people)

- irritation of the eyelids
- skin irritation

Some side effects are rare (may affect between 1 and 10 in every 10,000 people)

- difficulty in urinating
- impairment of memory or concentration, restlessness, disorientation, confusion, or hallucinations
- slight decrease in blood pressure

Some side effects are very rare (may affect less than 1 in every 10,000 people)

- skin rash

Other side effects (unknown frequency)

- application site burning

If you get any side effects which worry you (even effects not listed in this leaflet) remove the patch and talk to your doctor or pharmacist.

Eye Effects: Temporary blurring of vision and dilation (widening) of the pupils may occur, especially if traces of the drug are on your fingers or hands and come in contact with your eyes. Dry, itchy, or reddened whites of the eye and eye pain have been reported infrequently. In the unlikely event that you experience pain in the eye and reddened whites of the eye, which may be accompanied by widening of the pupil and blurred vision, remove the disc and consult your physician promptly. Widening of the

pupils and blurred vision without pain or reddened whites of the eye is usually temporary and not serious.

Possible Effects After Removing the Disc: There have been complaints of transient dizziness, nausea (feeling sick), vomiting (being sick), headache, and disturbances of balance following discontinuation of TRANSDERM-V*. If this happens, please consult a doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

DOSAGE

Only one TRANSDERM-V* disc can be used at any one time. Each disc may be worn for a maximum period of 3 days. Treatment with TRANSDERM-V* must not exceed six days, i.e. one disc worn for 3 days followed by a new disc worn for a second 3 days.

Apply one TRANSDERM-V* disc on the hairless area behind one ear approximately 12 hours before the drug's anti-nausea and anti-vomiting effect is needed. The disc may be worn for up to 3 days, and then it should be removed. If the disc is only needed for a shorter time, it should be removed at the end of the journey.

If you wish to control nausea for longer than 3 days, a second disc should be placed on a different skin site behind the other ear. The second disc may be worn for up to 3 days if needed.

Discontinue using TRANSDERM-V* once the second disc has been worn for 3 days.

HOW TO USE TRANSDERM-V*

1. Select a non-hairy area of skin on the head behind the ear, taking care to avoid a site containing any cuts or irritations. Wipe the area with a clean, dry tissue.
2. Each TRANSDERM-V* disc is individually sealed in a protective foil pouch. Before removing the disc from its pouch, be sure to wash your hands with soap and water.
3. Peel the foil pouch open and remove the tan-coloured disc complete with its clear plastic six-sided protective liner (Figure 1).



Figure 1

4. Holding the disc only by its edge - and taking care not to touch the adhesive surface (metallic side) with your hands - peel off the clear plastic protective liner. (Figure 2)



Figure 2

system disposable backing

5. Firmly apply the adhesive surface (metallic side) of the disc to the dry area of skin behind the ear so that the tan-coloured side is showing (Figure 3). Press firmly to make good contact especially around the edge. Once you have placed the disc behind your ear, do not touch it for the duration of desired use.

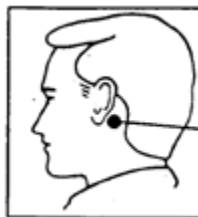


Figure 3

tan colored system

6. **Important: Be sure to wash your hands thoroughly with soap and water immediately after handling the disc, so that any drug that might get on your hands will not come into contact with your eyes (see Possible Side Effects).**
7. Remove the disc after 3 days and carefully dispose of it. (You may remove it sooner if you are no longer concerned about motion sickness.)
After removing the disc, be sure to wash your hands and the application site.
8. If you wish to control nausea for longer than 3 days, remove the first disc after 3 days and place a new disc on a different skin site behind the other ear. Use the same procedures and precautions described above. Discontinue using TRANSDERM-V* once the second disc has been worn for a maximum of 3 days.
9. Limited contact with water, as in bathing or swimming, will not affect the functioning of the disc. It is preferable, however, to keep the disc dry to prevent it from falling off.

In the unlikely event that the disc falls off, carefully discard it and put a new one behind the other ear.

IF YOU USE MORE TRANSDERM-V* THAN YOU SHOULD

If you accidentally apply too many patches at the same time, you may feel restless, excited or confused. In cases of higher overdose, you may become disorientated, hallucinate or have fits. In severe cases of overdose, coma and breathing difficulties may occur.

Remove the patch/patches immediately (as some overdose symptoms may persist for up to 24 hours or longer even after patch removal), and tell your doctor or contact your nearest casualty department immediately. Take any remaining patches with you.

STORAGE

TRANSDERM-V* should be stored at temperatures below 25°C. Do not freeze.

Do not store it out of the individually sealed pouch.

TRANSDERM-V* should be kept out of the reach of children and pets both before and after use. If your disc becomes stuck to a child or another person, remove the disc at once and contact a doctor.

The transdermal patch should be folded in half (sticky side inwards) before being discarded. Do not dispose of medicines via wastewater or household waste.

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