

SCOPOLAMINE TRANSDERMAL SYSTEM

scopolamine transdermal system 1 mg/3 days



What is in this leaflet

Please read this leaflet carefully before you start using Scopolamine Transdermal System.

This leaflet answers some common questions about Scopolamine Transdermal System.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Scopolamine Transdermal System against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Scopolamine Transdermal System is used for

Scopolamine Transdermal System is used for the prevention of symptoms of motion sickness, such as nausea (feeling sick), vomiting (being sick) and vertigo (loss of balance), which can occur when travelling by boat, plane, train or car.

This medicine belongs to a group of medicines called anti-emetics or anti-nauseants.

Scopolamine Transdermal System contains the active ingredient scopolamine (hyoscine).

Before you use Scopolamine Transdermal System

When you must not use it

Do not use Scopolamine Transdermal System if you:

- are allergic to scopolamine or any of the ingredients listed at the end of this leaflet
- have glaucoma.

Do not give this medicine to a child under the age of 10 years.

Safety and effectiveness in children younger than 10 years have not been established.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- have pyloric stenosis (a condition which affects your stomach)
- have difficulties when passing urine (e.g., due to enlargement of the prostate)
- have intestinal obstruction (partial or complete

blockage of the small or large intestine)

- are an elderly patient or have any metabolic, liver or kidney disease
- have or had pain in the eyes, blurred vision, or see rainbow-coloured halos around lights (this medicine should only be used after an eye examination by a doctor)
- have or have had epilepsy or epileptic seizures (increased number of fits have been reported)

Under these circumstances, Scopolamine Transdermal System may be unsuitable for you.

In rare cases, confusion and/or visual hallucinations may occur. Should this happen, remove Scopolamine Transdermal System at once and notify a doctor.

Take care after removing the patch, as side effects may persist for up to 24 hours or longer.

Remove patch before medical scans.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding. Your doctor can discuss with you the risks and benefits involved.

Use in elderly

Scopolamine Transdermal System can be used in the elderly although they may be more prone to experience side effects.

Use in hepatic and renal impairment

Scopolamine Transdermal System should only be used with caution with patients with liver or kidney function.

If you have not told your doctor about any of the above, tell them before you start using Scopolamine Transdermal System.

Using other medicines

Tell your doctor or pharmacist if you are using any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are using Scopolamine Transdermal System.

Some medicines may interfere with Scopolamine Transdermal System, these include:

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

These medicines may be affected by Scopolamine Transdermal System or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines.

Avoid drinking alcohol while using Scopolamine Transdermal System

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use Scopolamine Transdermal System

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

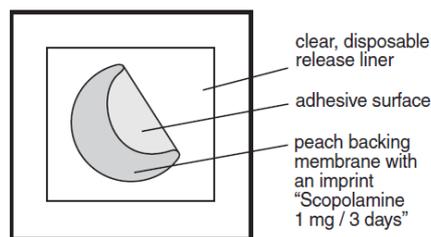
If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to use it

Always use this medicine exactly as described in this leaflet or as your pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

Apply one patch about 5 – 6 hours before embarking on a journey (or on the evening before the journey).

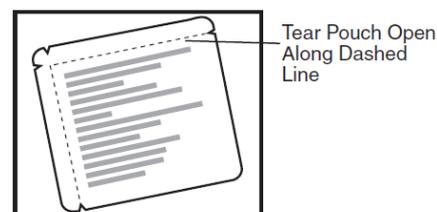
Inside the Scopolamine Transdermal System package, you will find one Scopolamine Transdermal System. An imprinted, peach backing membrane with a sticky surface is adhered to a clear, disposable release liner (See figure 1).



(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.

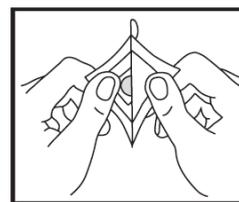
Tear along the dashed line on the Scopolamine Transdermal System package to open (See figure 2). Remove the contents of the pouch and discard the additional piece of clear protective film covering the transdermal system.



(Figure 2)

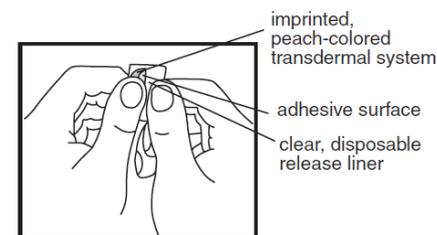
Remove the clear plastic release liner from the peach-coloured round

Scopolamine Transdermal System (See figure 3).



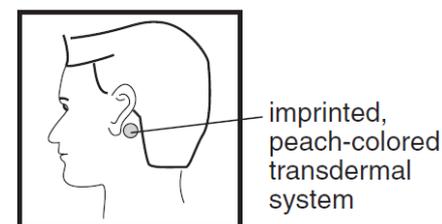
(Figure 3)

Do not touch the adhesive (sticky) surface on Scopolamine Transdermal System with your hands (See figure 4).



(Figure 4)

Apply the adhesive surface of Scopolamine Transdermal System firmly to the dry area of the skin behind your ear. The imprinted, peach coloured side of the 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 medicines from Scopolamine Transdermal System that gets on your hands will not get into your eyes.



(Figure 5)

Do not touch the patch again while it is being worn, since pressure exerted on it might possibly cause scopolamine (hyoscine) to ooze out at the edge. If you do touch the patch, wash your hands immediately. Do not cut the patch.

Wash your hands thoroughly afterwards. When you remove the patch, also wash the site of application. If you accidentally get

traces of the active substance in your eyes, rinse the eyes thoroughly with running water. You may experience temporary blurring of near vision and enlargement of the pupils (sometimes in one eye only).

How long to use it

Do not apply more than one patch at a time. Application of one patch is sufficient to ensure protection for up to 3 days. If your journey is of shorter duration, you should remove it earlier.

If you need more prolonged protection, remove the patch after 3 days and apply a fresh patch behind the other ear.

If you swim, take a shower, or wash your hair, this will not affect the adhesiveness or the action of the patch, provided you do not spend too long exposed to the water.

After removing Scopolamine Transdermal System:

Please note that the used Scopolamine Transdermal System will 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.

If you are not sure what to do, ask your doctor or pharmacist.

While you are using Scopolamine Transdermal System

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Scopolamine Transdermal System.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. It may affect other medicines used during surgery.

If you become pregnant while using this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are using this medicine. It may interfere with the results of some tests.

Things you must not do

Do not use Scopolamine Transdermal System to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Scopolamine Transdermal System affects you.

This medicine may cause effects such as feeling drowsy, confused, dizzy or may affect your vision in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you experience withdrawal symptoms, do not drive or operate machinery.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you use too much (overdose)

Remove the patch or patches, and immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest

hospital, if you think that you or anyone else may have used too much Scopolamine Transdermal System. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

if you accidentally apply too many patches at the same time, you may feel restless, excited, dry flushed skin, dry mouth, change in vision, fast or abnormal heartbeat, decreased bowel sounds, difficulty passing urine, high blood pressure, high body temperature, lack of energy and sleepiness or confused. In cases of higher overdose, you may become disorientated, hallucinate or have fits. In severe cases of overdose, coma and breathing difficulties or sudden loss of consciousness may occur. The symptoms of overdose may persist for up to 24 hours or longer, even after patch removal.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Scopolamine Transdermal System.

This medicine helps most people with symptoms of motion sickness, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Stop using Scopolamine Transdermal System and seek medical help immediately if you or your child has 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 and are very rare:

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

If you experience any of this, stop taking the medicine and **tell your doctor straight away.**

Some side effects are very common:

- 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:

- irritation of the eyelids
- skin irritation

Some side effects are rare:

- difficulty urinating
- impairment of memory or concentration, restlessness, disorientation, confusion, or hallucinations

The above list includes very serious side effects. Tell your doctor as soon as possible, you may need urgent medical attention or hospitalisation. These side effects are rare.

Some side effects are very rare:

- skin rash

Some side effects are of unknown frequency:

- reactions at the application site such as itching, redness and 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.

If you stop using Scopolamine Transdermal System

In rare cases, usually after several days of use, symptoms such as dizziness, nausea (feeling sick), vomiting (being sick), headache and disturbances of balance have been reported after discontinuation of treatment. If this happens, please consult a doctor.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Scopolamine Transdermal System

Storage

Keep your patch in the pack until it is time to use them.

If you take the patches out of the pack they may not keep well.

Keep your patches in a cool dry place where the temperature stays below 25°C.

Do not store Scopolamine Transdermal System or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Fold used patches in half (sticky side inwards), and discard in a way that nobody can touch them.

Do not dispose unused medicines via wastewater or household waste. If you stop taking this medicine or the expiry date has passed, take any unused medicine to your pharmacist for safe disposal.

Product description

What it looks like

A round opaque TDS with a peach-coloured backing printed with "Scopolamine 1 mg/3 days" in brown ink on an oversized removable release liner and with a clear overlay. The TDS is contained in a square pouch with printed paper on both sides. The pouch is labelled with the lot number and expiration date.

Ingredients

Active ingredient:

Scopolamine Transdermal System contains 1.5 mg of scopolamine as the active ingredient.

Inactive ingredients:

Scopolamine Transdermal System also contains:

- polyethylene/polyester film
- polypropylene
- povidone
- silicone adhesive
- brown imprinting ink

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Scopolamine Transdermal System is supplied in New Zealand by:

Viatris Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

04 April 2024 (Based on Scopolamine Transdermal System data sheet dated 04 April 2024).