

Scopoderm® TTS Patches

Hyoscine 1.5mg

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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1. What Scopoderm TTS Patches are and what they are used for

Scopoderm TTS Patches contain hyoscine which belongs to the group of medicines called anti-emetics or anti-sickness medicines. They are used to prevent the symptoms of motion sickness such as nausea (feeling sick), vomiting (being sick) and vertigo (loss of balance).

2. Before you use Scopoderm TTS Patches

Do not use Scopoderm TTS Patches if you:

- have glaucoma or a history of glaucoma (pressure behind the eye)
- are allergic to hyoscine or any of the other ingredients in the patch (see Section 6).

Take special care with Scopoderm TTS Patches if you:

- suffer from pyloric stenosis (a condition which affects your stomach)
- have problems urinating due to a bladder obstruction
- have a blockage of your intestines
- have a liver or kidney problem
- suffer from epilepsy (increased number of fits have been reported)
- are elderly.

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

Scopoderm TTS patches are not recommended for use in children under 10 years of age.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including those obtained without a prescription.

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

- drugs that act on the central nervous system (including alcohol)
- drugs that block nerve impulses
- other travel sickness medicines.

Using Scopoderm TTS Patches with food and drink

Do not drink alcohol whilst using the patches or until the effects of the patches have worn off (this may last up to 24 hours or longer from the time you have removed it).

Pregnancy and breast-feeding

Do not use Scopoderm TTS Patches during pregnancy and breast-feeding unless your doctor advises you to.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Scopoderm TTS Patches may make you feel drowsy, confused or dizzy and may affect your vision. Do not drive, operate any machinery or perform any activity that requires concentration. Care should be taken after removal of the patch as these effects may persist for up to 24 hours or longer.

3. How to use Scopoderm TTS Patches

Always use the patches exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults

One patch should be applied about 5-6 hours before leaving on your journey (or the evening before).

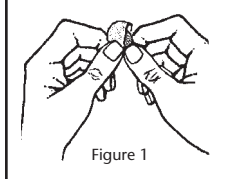


Figure 1

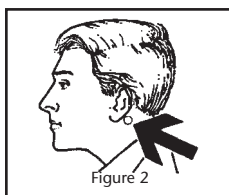


Figure 2

1. Remove the patch from the sachet. Peel off the clear, hexagonal plastic backing, holding the patch by its edge so as not to touch the sticky side (Figure 1).
2. Press the silver coloured sticky side of the patch firmly on to a clean, dry, hairless area of skin behind the ear (Figure 2). Avoid areas of skin that are cut or irritated in any way.
3. Wash your hands thoroughly after applying the patch. Do not touch the patch once it is in place as you may get the active ingredient on your fingers. If you do touch the patch, wash your hands **immediately**. Do not get the active ingredient near your eyes. If you get hyoscine on your fingers then touch your eyes, your vision may be temporarily affected.
4. Once your journey is over, take the patch off and dispose of it carefully.
5. When you take a patch off wash your hands and also the area of skin where the patch has been.

Each patch will last for up to 3 days. If you are travelling for more than three days, take the patch off after 3 days and apply a new one. You can swim, bathe or shower with little risk of the patch coming off, provided that you have applied the patch properly. However, it is best not to stay in the water too long. If the patch accidentally comes off, dispose of it carefully and put on a new patch.

Elderly

Scopoderm TTS Patches may be used in the elderly (see dosage for adults) although they may be more prone to suffer from the side-effects of hyoscine (see Section 4: Possible Side Effects).

Children

Scopoderm TTS patches can be used in children aged 10 years or over (see dosage for adults). The use of these patches is not recommended in younger children. See your doctor or pharmacist for alternative medicines.

If you use more Scopoderm TTS Patches than you should

If you accidentally use too many patches, 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, and tell your doctor or go to your nearest casualty department immediately. Take any remaining patches with you.

If you forget to use Scopoderm TTS Patches

If you forget to put a patch on, apply it as soon as you remember. Do not apply two patches at once to make up for the one that you forgot. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Scopoderm TTS Patches can cause side effects, although not everybody gets them.

The **most common** side effect is dryness in the mouth

Occasionally, you may experience the following side effects:

- irritation of the eyelids
- drowsiness
- irritation of the skin at the site of application.

In rare or isolated cases, the following have been reported:

- impairment of memory or concentration
- restlessness
- dizziness, disorientation, confusion
- problems in urinating (passing water)
- generalised skin rash
- dilatation of the pupils which can trigger glaucoma (pressure behind the eye)
- visual hallucinations

Side effects may persist up to 24 hours or longer after the patch is removed. Rarely, you may experience side-effects after you have taken off the patch.

These include:

- headache
- nausea (feeling sick)
- vomiting (being sick)
- loss of balance.

If any of the side effects gets serious, or if you have any side effects not listed in this leaflet, please tell your doctor or pharmacist.

These symptoms are more likely to occur if you have been wearing a patch for several days. If you are affected in this way, avoid any activities requiring concentration, e.g. driving, or operating machinery, until your symptoms have worn off.

Blurred vision and dilation of the pupils can occur if you get the active ingredient in your eyes. Therefore, to prevent this happening: **Always wash your hands after touching the patches.**

5. How to store Scopoderm TTS Patches

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not freeze the patches.

Do not remove from the protective pouch until you need it.

Do not use Scopoderm TTS Patches after the 'Expiry date' which is stated on the carton and pouch. The 'Expiry date' refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Scopoderm TTS Patches contain

The active ingredient in each patch is hyoscine 1.5mg (the average amount of hyoscine absorbed from each patch in 72 hours is 1mg).

The other ingredients are light mineral oil, polyisobutylene and polypropylene .

What Scopoderm TTS Patches look like and contents of the pack

Scopoderm TTS patches is a tan coloured, self adhesive, thin circular disc with a transparent protective film.

Each patch is individually packed into a foil pouch. Each cardboard carton contains two or five pouches, not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Novartis Consumer Health UK Limited

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For any information about this medicinal product, please contact the Marketing Authorisation Holder.

This medicinal product is authorised in the Member States of the EEA under the following names:

This leaflet was last approved in November 2011.