

Package Leaflet: Information for the User
Scopoderm® 1.5 mg Patches
(hyoscine)

Your medicine is known by the above name, but will be referred to as Scopoderm® Patches throughout this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet

1. What Scopoderm® Patches are and what they are used for
2. What you need to know before you use Scopoderm® Patches
3. How to use Scopoderm® Patches
4. Possible side effects
5. How to store Scopoderm® Patches
6. Contents of the pack and other information

1. WHAT SCOPODERM® PATCHES ARE AND WHAT THEY ARE USED FOR

Scopoderm® Patches contain the active substance 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), which can occur when travelling by boat, train or car.

Travel sickness occurs when your body's internal balancing system becomes confused by receiving different messages – your eyes say one thing about the position of your body, but your balance mechanisms tell you differently. Anyone can suffer from travel sickness: children are more prone but often grow out of it as they get older.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE SCOPODERM® PATCHES

Do not use Scopoderm® Patches if you:

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

Warnings and precautions

Talk to your doctor or pharmacist before using Scopoderm® Patches if you:

- suffer from pyloric stenosis (a condition which affects your stomach)
- have problems urinating – for example due to a bladder obstruction or diseases of the prostate
- have a blockage of your intestines
- are an elderly patient or have any metabolic, liver or kidney disease
- suffer from epilepsy (increased number of fits have been reported)
- have had pain in the eyes, blurred vision, or see rainbow-coloured halos around light. (Scopoderm® Patches should only be used after an eye examination by a doctor).

Care should be taken after removal of the patch as side effects may persist for up to 24 hours or longer under these circumstances, Scopoderm® patches may be unsuitable for you.

- Remove the patch before a medical scan as aluminium is present in one of the patch layers.
- Do not cut the patch.
- Dispose of used patches carefully.
- Do not apply more than one patch at a time.
- After handling the Scopoderm® patch you should carefully wash your hands and application site

Children

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

Other medicines and Scopoderm® Patches

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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:

- alcohol
- other drugs acting on the brain

- antiallergic medicines
- antidepressants
- antiparkinsons and antivirals
- antiarrhythmics
- other travel sickness medicines.

Scopoderm® Patches with food, drink and alcohol

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

If you are pregnant or breastfeeding, you should talk to your doctor. Do not use 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® Patches may make you feel drowsy, confused or dizzy and may affect your vision or give rise to any other adverse reactions which may adversely affect your reaction. 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® PATCHES

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not exceed the recommended dose.

Adults and the elderly

One patch should be applied about 5-6 hours before leaving on your journey (or the evening before) to a clean, dry, hairless area of intact skin behind the ear.

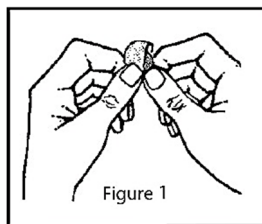


Figure 1

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.

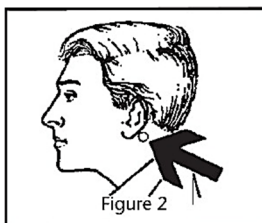


Figure 2

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 fresh patch behind the other ear. 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.

Use in the elderly

If you are elderly, you may be more prone to suffer from the side effects of hyoscine (see Section 4: Possible Side Effects).

Use in children

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® 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 experience rise in body temperature after using the Scopoderm® Patch you should take immediate action to lower body temperature (cold baths are recommended).

If you forget to use Scopoderm® 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 stop using Scopoderm® Patches

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 the treatment. 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 and consult a doctor.

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

4. POSSIBLE SIDE EFFECTS

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

STOP using Scopoderm® 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 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
- Frequently 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 1,000 people)

- Difficulty in passing water (urinating)
- Impairment of memory or concentration, restlessness, disorientation, confusion, or hallucinations.

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

- Skin rash

There are some side effects with not known frequency (frequency cannot be estimated from the available data)

- Agitation, co-ordination abnormalities, headache
- Increase in body temperature due to decreased sweating.
- Reactions at the application site such as rash, itching, redness and burning.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE SCOPODERM® PATCHES

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Do not freeze.
- Do not remove from the protective pouch until you need it.
- The transdermal patch should be folded in half (sticky side inwards) before being discarded.
- If the patch becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Scopoderm® Patches contain

The active ingredient in the Scopoderm® is scopolamine (hyoscine). Each transdermal patch contains a total of 1.5 mg scopolamine (hyoscine).

Average absorption rate 1 mg scopolamine (hyoscine) in 72 hours.

The other ingredients are polyisobutylene, light mineral oil, pigmented polyethylene/aluminised polyester film, polypropylene film and polyester siliconised.

What Scopoderm® Patches look like and contents of the pack

Scopoderm® is a flat, round patch approximately 1.8 cm in diameter. One side of the patch is tan; the other side is silver and is placed on an oversized clear hexagonal film.

Each patch is individually packed into a foil pouch.

Pack sizes available 2 patches.

Manufactured by GlaxoSmithKline Consumer Healthcare GmbH & Co. KG, Barthstrasse 4, 80339 Munich, Germany.

or

Famar Ave's Avlon Plant (48th), 48th KM National Road, Athens-Lamia, Avlona Attiki 19011, Greece.

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Revision date: 18.10.2024

PLGB 16378/0756



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