

Package leaflet: Information for the user

Stieprox® 15 mg/g Shampoo

ciclopirox olamine

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- In this leaflet, Stieprox 15 mg/g Shampoo will be called Stieprox.

What is in this leaflet

1. What Stieprox is and what it is used for
2. What you need to know before you use Stieprox
3. How to use Stieprox
4. Possible side effects
5. How to store Stieprox
6. Contents of the pack and other information

1. What Stieprox is and what it is used for

Stieprox contains the active substance ciclopirox olamine. This belongs to a group of medicines called 'anti-fungals'. Stieprox is used to treat scalp disorders such as dandruff and seborrhoeic dermatitis (red, flaky, itchy scalps) in adults and adolescents aged over 12 years.

2. What you need to know before you use Stieprox

Do not use Stieprox

- If you are allergic to ciclopirox olamine or any of the other ingredients in this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Stieprox

- If you have grey, white or damaged hair. This is because Stieprox may affect the colour of your hair.

Stieprox is for external use only.

Stieprox may cause stinging and irritation to the eyes. If you accidentally get Stieprox in your eyes, wash the affected area with water.

Stieprox may cause skin irritation. If irritation occurs and persists, treatment should be discontinued.

If you are not sure if the above applies to you, talk to your doctor or pharmacist before using Stieprox.

Children

Do not use this medicine on children under 12 years of age because the safety and efficacy have not been established.

Other medicines and Stieprox

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This includes medicines you buy without a prescription, such as herbal medicines.

Pregnancy and breast-feeding

Pregnancy:

- There is no information about the safety of Stieprox in pregnant women.

Breast-feeding:

- It is not known whether the ingredients of Stieprox can pass into breast milk.
- Ensure that you wash off all traces of Stieprox from your breasts before you begin breast-feeding.

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Important information about some of the ingredients of Stieprox

This medicine contains fragrance (AF1050) with allergens: Linalool, Alpha-Isomethyl ionone (3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one), Citronellol, Hexyl cinnamal (Hexyl cinnamaldehyde), Benzyl salicylate, Benzyl benzoate, Coumarin, Eugenol, Geraniol, Hydroxycitronellal, Isoeugenol, Butylphenyl methylpropional (Lilial), Limonene, Benzyl alcohol, Amyl cinnamal, Amylcinnamyl alcohol, Anisyl alcohol (Anise alcohol), Benzyl cinnamate, Cinnamal, Cinnamyl alcohol, Citral, Farnesol.

Allergens may cause allergic reactions.

3. How to use Stieprox

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Only use Stieprox on your hair and areas next to your hairline.
- Use Stieprox two to three times a week.
- Your doctor will tell you how long to use this medicine, usually it is for four weeks.
- You can use a mild shampoo on the days when you are not using Stieprox.

How to apply Stieprox

1. Wet your hair.
2. Use enough Stieprox so that the lather covers your scalp, hair and adjacent areas, if affected.
3. Massage the scalp and adjacent areas, if needed, really well using your fingertips.
4. Rinse your scalp and hair thoroughly.
5. Repeat steps 2 to 4.
6. Leave the Stieprox on your scalp for three to five minutes over the two applications.

If you forget to use Stieprox

If you forget to use Stieprox, apply the next day.

If you accidentally swallow Stieprox

The ingredients of Stieprox are not expected to be harmful if swallowed in the small amounts. If you do accidentally get Stieprox in your mouth, rinse at once with water. If you accidentally swallow a large amount of Stieprox, contact your doctor or pharmacist for advice.

Try not to get Stieprox in your eyes. If this happens, rinse well with clean water.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common: may affect up to 1 in 10 people

- skin irritation at the application site including, itching, burning sensation, redness and rash

Rare: may affect up to 1 in 1,000 people

- allergic reaction at or around the site of application
- flaking of the skin
- eczema (itchy skin rash)
- unusual hair loss or thinning
- changes to hair colour and/or texture

Some of these effects can also be symptoms of the condition you are treating. However, if you experience any of these effects for the first time after starting to use Stieprox, or you experience worsening of these effects, stop using Stieprox and tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Stieprox

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Stieprox contains

- The active substance is ciclopirox olamine. Each gram of shampoo contains 15 mg ciclopirox olamine.
- The other ingredients are sodium lauryl ether sulphate, cocamidopropyl betaine, sodium monohydrogen phosphate dodecahydrate, citric acid monohydrate, coconut diethanolamide, hexylene glycol, oleyl alcohol, polysorbate 80, polyquaternium 10, fragrance AF17050 (contains Linalool, Alpha-Isomethyl ionone (3-Methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one), Citronellol, Hexyl cinnamal (Hexyl cinnamaldehyde), Benzyl salicylate, Benzyl benzoate, Coumarin, Eugenol, Geraniol, Hydroxycitronellal, Isoeugenol, Butylphenyl methylpropional (Lilial), Limonene, Benzyl alcohol, Amyl cinnamal, Amylcinnamyl alcohol, Anisyl alcohol (Anise alcohol), Benzyl cinnamate, Cinnamal, Cinnamyl alcohol, Citral, Farnesol and dipropylene glycol), sodium hydroxide, purified water.

What Stieprox looks like and contents of the pack

Stieprox is a clear, straw to light-orange coloured shampoo. Stieprox is available in a plastic bottle with plastic screw cap containing 100 ml shampoo. Each pack contains 1 bottle.

Manufacturer:

Delpharm Bladel B.V., Bladel, The Netherlands.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation number: PPA 465/490/1

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