

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

SEBIPROX 1.5% SHAMPOO

Ciclopirox olamine

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Sebiprox Shampoo carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 4 weeks.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Sebiprox Shampoo is and what it is used for
2. Before you use Sebiprox Shampoo
3. How to use Sebiprox Shampoo
4. Possible side effects
5. How to store Sebiprox Shampoo
6. Further information

1. WHAT SEBIPROX SHAMPOO IS AND WHAT IT IS USED FOR

Sebiprox Shampoo contains a medicine called ciclopirox olamine. This belongs to a group of medicines called 'anti-fungals'. Sebiprox Shampoo is used for red, scaly itchy scalps (called seborrhoeic dermatitis).

2. BEFORE YOU USE SEBIPROX SHAMPOO

Do not use Sebiprox Shampoo

- if you are **allergic** (hypersensitive) to ciclopirox olamine or any of the other ingredients in Sebiprox Shampoo (listed in Section 6).

If you are not sure, talk to your doctor or pharmacist before using Sebiprox Shampoo.

Take special care with Sebiprox Shampoo

- Sebiprox Shampoo is for external use only.
- Check with your doctor or pharmacist before using this shampoo if you have grey, white or chemically damaged hair (for example, due to hair dye). This is because Sebiprox Shampoo may, in rare instances, affect the colour of your hair.
- **Sebiprox Shampoo is not recommended for children aged under 12.** This is because its safety and effectiveness are not known in this age group.
- **Try not to get Sebiprox Shampoo in your eyes. It may cause stinging and irritation.** If you accidentally get Sebiprox Shampoo in your eyes **wash the affected area** with water.

Using other medicines

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

Pregnancy and breast-feeding

Do not use this medicine if you are **pregnant** or **breast feeding**.

There is no information about the safety of Sebiprox Shampoo in pregnant women.

- **Tell your doctor if you are pregnant** or planning to become pregnant.
- **If you do become pregnant during treatment** with Sebiprox Shampoo, tell your doctor.

Driving and using machines

There are no restrictions on driving and using machines with Sebiprox Shampoo.

Important information about some of the ingredients of Sebiprox Shampoo

Sebiprox Shampoo contains dipropylene glycol (contained in fragrance AF 17050). This may cause skin irritation in some people.

3. HOW TO USE SEBIPROX SHAMPOO

- Use Sebiprox Shampoo two to three times a week for four weeks.
- Only use Sebiprox Shampoo on your hair, scalp and adjacent areas, if also affected.
- You can use a mild shampoo on the days you are not using Sebiprox Shampoo.

How to apply Sebiprox Shampoo

1. Wet your hair
 2. Use enough Sebiprox Shampoo so that it covers your scalp and hair and adjacent areas, if also affected. Massage the scalp and adjacent areas, if needed, really well, using your fingertips.
 3. Rinse your scalp and hair thoroughly.
 4. Repeat steps 2 to 4. Sebiprox Shampoo should be in contact with your scalp for a total time of three to five minutes over the two applications.
- Try not to get Sebiprox Shampoo in your eyes. If this happens, rinse well with clean water.

If you accidentally swallow Sebiprox Shampoo

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sebiprox Shampoo can cause side effects, although not everybody gets them.

Side effect may occur with certain frequencies, which are defined as follows:

- very common: may affect more than 1 in 10 people
- common: may affect up to 1 in 10 people
- rare: may affect up to 1 in 1000 people

The following side effects have been observed with Sebiprox Shampoo

Very common:

- skin irritation*
- itching*

Common:

- rash*

- burning sensation
- redness at the application site*

Rare:

- allergic reaction
- flaking of the skin*
- eczema (itchy skin rash)*
- hair loss*
- hair colour changes
- hair texture changes (dry, matted or dull hair)

Some of these effects (marked with “*”) can also be symptoms of the condition you are treating. Therefore, if you experience any of these effects for the first time after starting to use Sebiprox Shampoo, or you experience worsening skin irritation, redness, or itching, stop using the product 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 www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SEBIPROX SHAMPOO

Keep out of the reach and sight of children.

There are no special precautions for storage.

Do not use Sebiprox Shampoo after the expiry date which is stated on the bottle and the outer packaging. 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 Sebiprox Shampoo contains

- The active ingredient is ciclopirox olamine 1.5 g per 100 g
- The other ingredients are sodium lauryl ether sulphate, cocamidopropyl betaine, disodium phosphate, dodecahydrate, citric acid monohydrate, coconut diethanolamide, hexylene glycol, oleyl alcohol, polysorbate 80, polyquaternium-10, fragrance AF17050 (including dipropylene glycol), sodium hydroxide, purified water.

What Sebiprox Shampoo looks like and contents of the pack

Sebiprox Shampoo is a clear yellow to light orange shampoo supplied in bottles of 60ml, 100ml, 125ml, 150ml, 250ml, 350ml or 500ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Stiefel Laboratories (Ireland) Limited
Finisklin Business Park
Sligo, Ireland.

Manufactured by:

Stiefel Laboratories (Ireland) Limited
Finisklin Business Park
Sligo, Ireland.

Famar Nederland B.V
Industrieweg 1
5531 AD BLADEL
The Netherlands

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

Austria: Stieprox 1,5% Shampoo
Cyprus: Stieprox 1.5% Σαμπουάν
Czech Republic: StieproxDenmark: Sebiprox
Denmark: Sebiprox 1.5% Shampoo
Finland: Stieprox 1.5% Shampoo
France: Sebiprox 1.5% Shampooing
Germany: Sebiprox 1,5% Loesung
Greece: Stieprox Shampoo 1.5%
Italy: Sebiprox 1,5% Shampoo
Latvia: Stieprox 1.5% Shampoo
Lithuania: Stieprox 1.5% šampūnas
Malta: Sebiprox 1.5% Shampoo
Norway: Sebiprox 1,5% Sjampo
Portugal: Sebiprox
Slovakia: Stieprox 1.5% Shampoo
Spain: Sebiprox 1,5% champú
Sweden: Sebiprox 1,5% schampo

This leaflet was last approved in 07/2015.