

CONSUMER MEDICINE INFORMATION

STIEPROX® Liquid (1.5% w/w Ciclopirox Olamine)

Please read the leaflet carefully before using STIEPROX Liquid. It contains a summary of information available on STIEPROX Liquid. It does not contain all the available information. All medicines have benefits and risks. If you have any questions about using STIEPROX Liquid after reading this leaflet, please ask your *doctor* or *pharmacist*.

What is in STIEPROX Liquid?

STIEPROX Liquid contains *Ciclopirox Olamine* 1.5% w/w as the active ingredient. *Ciclopirox Olamine* is a broad-spectrum antifungal agent that inhibits the growth of the yeast known as *Pityrosporum ovale* or *Pityrosporum orbiculare*, which is associated with conditions such as dandruff and seborrhoeic dermatitis.

STIEPROX Liquid also contains sodium laureth sulfate 70%, cocamidopropyl betaine, sodium phosphate – dibasic dodecahydrate, citric acid monohydrate, cocamide DEA, hexylene glycol, oleyl alcohol, polysorbate 80, polyquaternium-10, fragrance AF17050, sodium hydroxide and purified water.

STIEPROX Liquid comes in a bottle containing 60ml or 150ml of a clear, yellow to light orange coloured liquid.

What is STIEPROX Liquid used for?

STIEPROX Liquid is used for the treatment of *dandruff* and *seborrhoeic dermatitis* affecting the scalp.

It also helps to reduce the formation of scales and flakes and remove those that have already formed.

Dandruff is a skin condition that is characterised by excessive scaling of the scalp. It presents itself as dry whitish scales generally without red or inflamed skin. *Dandruff* is more obvious when the scales become trapped in your hair and drop on to your clothing.

Seborrhoeic dermatitis is considered a severe form of *dandruff*. People who have *seborrhoeic dermatitis* generally have red, itchy and scaling areas on the scalp and possibly on other areas of the body, such as the face, eyebrows, beard area, upper chest and back and in the underarm area.

When must STIEPROX Liquid not be used?

STIEPROX Liquid may not be right for some people. Do not use STIEPROX Liquid if you are hypersensitive to (have had an allergic reaction to) ciclopirox olamine/ciclopirox or any of the other ingredients. If in any doubt ask your *doctor* or *pharmacist* for advice.

Before using STIEPROX Liquid

Tell your *doctor* if:

- You are pregnant or intend to become pregnant.
- You are breast-feeding or planning to breast-feed.

STIEPROX Liquid is not recommended for pregnant or breast-feeding women. Your doctor will discuss the risks and benefits of using STIEPROX Liquid if you are pregnant or breast-feeding.

If you do breast-feed your baby while you are using STIEPROX Liquid, ensure that you wash off all traces of STIEPROX Liquid from your breasts after bathing/showering before you begin breast-feeding.

Tell your doctor if you are allergic to ciclopirox olamine or any of the ingredients in STIEPROX Liquid listed at the beginning of this leaflet.

You should not allow STIEPROX Liquid to come into contact with your eyes; STIEPROX Liquid is for external use only. If STIEPROX Liquid comes into contact with your eyes, wash thoroughly with water.

In order to avoid possible interactions between several medicines, please inform your *doctor* or *pharmacist* if you are taking or have recently taken any other medicines, even those not prescribed.

STIEPROX Liquid is not recommended for use in children under 12 years of age.

How should STIEPROX Liquid be used?

STIEPROX Liquid is for use by adults and children 12 years and over. STIEPROX Liquid is for topical application to the scalp. The hair should be wetted and sufficient STIEPROX Liquid applied to produce an abundant lather. The scalp and adjacent areas should be vigorously massaged with the fingertips. Rinse thoroughly and repeat the procedure. Over the two applications, the shampoo should be left in the hair for a total time of 3 to 5 minutes.

STIEPROX Liquid should be used two to three times weekly for 4 weeks. STIEPROX Liquid will provide temporary relief during the period of use and dandruff and/or seborrhoeic dermatitis may recur if treatment is discontinued.

You can use a mild shampoo on the days you are not using STIEPROX Liquid.

If your *doctor* or *pharmacist* has recommended other ways of using STIEPROX Liquid you should follow their advice.

STIEPROX Liquid contains a hair conditioner, but you can use a separate conditioner after STIEPROX Liquid if you wish.

If you forget to use STIEPROX Liquid, just apply the next day instead.

In case of accidental ingestion, contact the Poisons Information Centre (Phone 13 11 26 for Australia; for New Zealand phone 0800 POISON or 0800 764 766) for advice. Avoid contact with the eyes. If STIEPROX Liquid comes into contact with your eyes, wash thoroughly with water.

Are there any unwanted effects of STIEPROX Liquid?

Like all medicines, STIEPROX Liquid can cause side effects, but not everybody gets them.

Common side effects

These may affect up to 1 in 10 people.

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

Uncommon side effects

These may affect up to 1 in 100 people.

- redness at the application site.

Rare side effects

These 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

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 Liquid, or you experience worsening of these effects, stop using STIEPROX Liquid and tell your doctor or pharmacist.

- STIEPROX Liquid may cause your hair to change colour if you have grey, white or chemically damaged hair (for example, due to hair dye).

Check with your doctor or pharmacist before using this shampoo if you think this may apply to you. Your doctor or pharmacist will decide whether STIEPROX Liquid is suitable for you.

If you get side effects

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

Where should you store STIEPROX Liquid?

Store STIEPROX Liquid below 30°C.

As with all medicines you should keep STIEPROX Liquid out of the reach of children.

An expiry date is printed on the bottle. Do not use the STIEPROX Liquid after this date.

If STIEPROX Liquid has passed its expiry date, dispose of it safely by returning it to your local *pharmacist*.

Australian Registration Number
AUST R 95879

Manufacturer

STIEPROX Liquid is manufactured in Singapore for
Stiefel Laboratories Pty Ltd.
Unit 2/10 Salisbury Road
CASTLE HILL NSW 2154.
Ph: (02) 9894 5088
Toll Free: 1800 251 075
e-mail: StiefelAustralia@stiefel.com

Distributed in New Zealand by:
David Sparks Ltd
4 Tolich Place
Henderson, Auckland
Telephone: (09) 835 3919

STIEPROX® is a registered trade mark of Stiefel Laboratories, Inc.

This document was prepared in March 2011.

Version 2.0