

Data Sheet

STIEPROX® Liquid

NAME OF MEDICINE

STIEPROX Liquid

STIEPROX Liquid contains 1.5% w/w ciclopirox olamine in a shampoo base for topical application.

PRESENTATION

STIEPROX Liquid is a clear, yellow to light orange coloured, viscous liquid.

USES

Actions

Ciclopirox olamine is an antifungal agent (pyridones family), which is active *in-vitro* inhibiting the growth of various fungal species including the yeast *Malassezia furfur* (formerly known as *Pityrosporum ovale* or *Pityrosporum orbiculare*). The latter has been implicated as a causative organism in dandruff and seborrhoeic dermatitis. Ciclopirox olamine also exhibits some anti-inflammatory activity.

Pharmacokinetics

Topical application of ciclopirox olamine as a 1% cream to human skin showed that the percutaneous absorption is very low: 1.1% to 1.7% of the applied dose was detected in urine.

The potential for systemic absorption of ciclopirox olamine from a wash-off shampoo containing 1.5% ciclopirox olamine is low.

Indications

STIEPROX Liquid is indicated for the treatment of dandruff and mild to moderate seborrhoeic dermatitis.

DOSAGE AND ADMINISTRATION

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. Leave in hair then thoroughly rinse and repeat 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. STIEPROX Liquid will provide temporary relief during the period of use and dandruff and/or seborrhoeic dermatitis may recur if treatment is discontinued.

The recommended treatment period is 4 weeks.

A mild shampoo may be used in between applications of STIEPROX Liquid.

CONTRAINDICATIONS

Patients with known hypersensitivity to ciclopirox, ciclopirox olamine or any of the other ingredients (see *Further Information*).

WARNINGS AND PRECAUTIONS

STIEPROX Liquid is for external use only.

Ciclopirox olamine may cause eye irritation. In case of accidental contact with the eyes, rinse with water.

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

In rare instances, mainly in patients with chemically damaged (for example, due to hair dye), grey or white hair, a discolouration of the hair has been observed.

Pregnancy and Lactation

No teratogenic effect has been observed during studies done on animals. The safety of STIEPROX Liquid in pregnant and lactating women has not been established.

Effects On Ability To Drive And Use Machines

Very unlikely to produce any effect.

Use for Children

Safety and effectiveness in children under 12 years of age have not been established.

ADVERSE EFFECTS

Clinical Trial Data.

The following convention has been used for the classification of adverse reactions:

Very common $\geq 1/10$

Common $\geq 1/100$ to $< 1/10$

Uncommon $\geq 1/1000$ to $< 1/100$

Rare $\geq 1/10,000$ to $< 1/1000$

Very rare $< 1/10,000$

Skin and subcutaneous tissue disorders

Common: Application site irritation including pruritus, burning sensation and application site rash*

Uncommon: Erythema*

Postmarketing data

Immune system disorders

Rare: Application site hypersensitivity

Skin and subcutaneous tissue disorders

Rare: Skin exfoliation*

Eczema

Alopecia*

Hair colour changes

*Since these effects are also symptoms of the underlying disease, it is expected that these adverse reactions would manifest as worsening of symptoms.

INTERACTIONS

None known.

OVERDOSAGE

Management should be as clinically indicated.

In case of accidental ingestion, contact the Poisons Information Centre on 0800 POSION or 0800 764 766 for advice.

PHARMACEUTICAL PRECAUTIONS

Incompatibilities

None.

Shelf Life

Three years.

Special precautions for storage

None.

Storage temperature

Store below 30°C.

MEDICINE CLASSIFICATION

Pharmacy Only Medicine

PACKAGE QUANTITIES

STIEPROX Liquid is presented in 60 ml and 150 ml high-density polyethylene bottles fitted with flip-top screw caps.

FURTHER INFORMATION

Excipients

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

Trade Mark

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

NAME AND ADDRESS

Manufacturer

Stiefel Laboratories (Pte) Ltd
103 Gul Circle
Jurong
Singapore 629589

Distributed by

David Sparks Ltd
PO Box 83-122
Edmonton,
Auckland, New Zealand

Tel: (09)835 3919

Fax: (09)835 3918

DATE OF PREPARATION

April 2011

Version 2.0