Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Stieprox 15 mg/g Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of shampoo contains 15 mg/g ciclopirox olamine.

Excipients with known effect:

Fruitier timotei AF17050 contains allergens (see section 6.1)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Shampoo.

Clear, straw to light-orange coloured, viscous shampoo.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Stieprox is indicated in the treatment of scalp disorders such as dandruff and seborrhoeic dermatitis.

4.2 Posology and method of administration

Adults and adolescents aged over 12 years:
Stieprox is only for topical application to the scalp and adjacent areas.

The hair should be wetted and sufficient Stieprox applied to produce an abundant lather. The scalp and adjacent areas should be vigorously massaged with the fingertips. The hair should then be thoroughly rinsed and the procedure repeated. The shampoo should remain in contact with the scalp for a total contact time of 3-5 minutes over the two applications.

Stieproxshould be used two to three times weekly or as often as necessary for the treatment of scalp disorders. A mild shampoo can be used in between applications of Stieprox.

The recommended treatment period is 4 weeks.

Elderly patients:
The dosage instructions given above are suitable for the elderly.

Paediatric population:
The safety and efficacy of Stieprox in children under 12 years of age have not been established.

4.3 Contraindications

Hypersensitivity to the active substance,ciclopirox olamine,or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Stieprox is for external use only.

As with all shampoo products avoid contact with eyes. Ciclopirox olamine may cause eye irritation. In case of accidental contact with the eyes, rinse with water.

Stieprox 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 discoloration of the hair has been observed.

This medicine contains fragrance (Fruitier timotei AF17050) 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

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
The safety of ciclopirox olamine during human pregnancy has not been established. Studies in animals given oral or subcutaneous ciclopirox olamine did not reveal any developmental toxicity.
No effects during pregnancy are anticipated since systemic exposure is low.

Breast-feeding
It is not known if ciclopirox olamine is excreted in human milk. Risk to the infant is likely to be low since systemic exposure is low.

Patients should be advised to ensure that any residual product is fully washed off the breast prior to breast-feeding.

Fertility
Studies in animals given oral or subcutaneous ciclopirox olamine did not reveal any impairment of fertility.

4.7 Effects on ability to drive and use machines

Stieprox has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Clinical trial data

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

Very common ≥1/10
Common ≥1/100 to <1/10
Uncommon ≥1/1000 to <1/100
Rare ≥1/10000 to <1/1000
Very rare <1/10000

Skin and subcutaneous tissue disorders

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

Post-marketing

Immune system disorders

Rare: Application site hypersensitivity

Skin and subcutaneous tissue disorders

Rare: Skin exfoliation*
Eczema
Alopecia*
Hair colour changes
Hair texture changes*

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

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie

4.9 Overdose

Symptoms
There is currently limited experience of accidental oral ingestion with ciclopirox olamine.

Management
Management should be as clinically indicated or as recommended by the National Poisons Information Centre of Ireland. There is no specific treatment for accidental oral ingestion of ciclopirox olamine. If accidental oral ingestion occurs, the patient should be treated supportively with appropriate monitoring as necessary.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: other antifungals for topical dermatological use.
ATC code: D01AE14.

Mechanism of action
Ciclopirox olamine is a hydroxypyridone antifungal agent which is active *in vitro* inhibiting the growth of various fungal species including the yeast *Malassezia furfur* (formerly known as *Pityrosporumovale* 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.

Pharmacodynamic effects
Ciclopirox olamine 1.5% shampoo shows *in vivo* antifungal activity against *Malassezia* spp.
A clinical study has shown that ciclopirox olamine 1.5% shampoo significantly reduced the count of *Malassezia furfur spp.* in samples obtained from the scalp of subjects with dandruff and/or seborrhoeic dermatitis.

5.2 Pharmacokinetic properties

Absorption
The potential for clinically significant systemic absorption of ciclopirox olamine from a wash-off shampoo containing 1.5% ciclopirox olamine is expected to be low.

Distribution
Following oral administration of ciclopirox olamine to humans, affinity of ciclopirox olamine to serum proteins was found to be 96±2% in the concentration range of 0.01 to 11.0 µg/mL.

Metabolism
The metabolic patterns after oral and dermal application are similar. Glucuronidation of ciclopirox olamine appears to be the major form of its metabolism.

Elimination
Following oral administration of ciclopirox olamine to humans, 96% of the administered dose is excreted within 12 hours. Ciclopirox olamine is excreted in urine with approximately 80% of an oral dose excreted as the glucuronide metabolite.

5.3 Preclinical safety data

Ciclopirox olamine has been in use for twenty years. It is used in leave-on topical antifungal preparations and vaginal creams. Studies have not demonstrated any prohibitive findings in reproduction toxicology, mutagenicity, carcinogenicity or phototoxicity.

Carcinogenicity
A dermal carcinogenic study in mice at concentrations of 1% and 5% ciclopirox olamine formulated in polyethylene glycol 400 applied to the intact skin, twice a week, for one year, followed by a six-month non-treatment period was conducted. No tumours were observed in any of the mice at the site of application. Overall incidence of neoplasms was similar among the treated and control groups. In addition, there is no evidence that ciclopirox olamine is carcinogenic following oral or subcutaneous administration to a number of animal species.

Mutagenicity
Ciclopirox olamine did not cause gene mutation or chromosomal damage in several bacterial mutagen assays or in two mammalian assays. In a battery of *in vitro* genotoxicity assays with ciclopirox free acid, one assay was weakly positive. The weight of evidence provided by the *in vitro* and *in vivo* assessments suggest that ciclopirox does not present a genotoxic hazard to humans.

Reproductive toxicology
Reproductive studies in mice, rats, rabbits and monkeys, at doses of ciclopirox olamine 10 times that of a topical human dose, have revealed no significant evidence of impaired fertility or harm to the foetus. There is evidence that ciclopirox olamine crosses the placental barrier in animals.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium lauryl ether sulphate 70%
Cocamidopropyl betaine
Disodium phosphate dodecahydrate
Citric acid monohydrate (for pH-adjustment)
Coconut diethanolamide
Hexylene glycol
Oleyl alcohol
Polysorbate 80
Polyquaternium 10
Fruitier timotei AF17050 (fragrance – contains allergens and dipropylene glycol)
Sodium hydroxide (for pH-adjustment)

Purified water

Fruitier timotei AF17050 contains 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.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

High density polyethylene bottles fitted with polypropylene screw caps containing 20 ml or 100 ml shampoo.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline (Ireland) Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1077/130/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5th October 2001

Date of last renewal: 5th October 2006

10 DATE OF REVISION OF THE TEXT

June 2021