

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 ciclopirox olamine.

Excipients with known effect:

Fragrance AF17050 containing 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).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Shampoo

Product imported from Austria

Clear, straw to light orange coloured, shampoo.

4 CLINICAL PARTICULARS

As per PA1077/130/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1077/130/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the bottle and outer carton of the product as marketed in the country of origin.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Plastic bottle with plastic screw cap containing 100 ml shampoo.

Pack size: 1 bottle.

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 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/490/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st January 2022

10 DATE OF REVISION OF THE TEXT