

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Soolantra 10 mg/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of cream contains 10 mg of ivermectin.

Excipient(s) with known effect:

One gram of cream contains cetyl alcohol, stearyl alcohol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and propylene glycol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.

Product imported from Germany:

White to light yellow cream.

4 CLINICAL PARTICULARS

As per PA22743/015/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22743/015/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Isopropyl palmitate
Carbomer Type B
Dimeticone
Sodium edetate
Citric acid monohydrate
Cetyl alcohol
Stearyl alcohol
Macrogol cetostearyl ether
Sorbitan stearate
Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Phenoxyethanol
Propylene glycol
Oleyl alcohol
Sodium hydroxide
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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The shelf-life expiry date for this product shall be the date shown on the tube and outer package of the product on the market in the country of origin.

After first opening: use within 6 months.

6.4 Special precautions for storage

This medicinal product does not require any special storage condition.

6.5 Nature and contents of container

Plastic white tube with child resistant closure.

Pack size: 1 tube of 45 g.

6.6 Special precautions for disposal

Mitigation measures should be taken in order to prevent or reduce contamination, in particular the aquatic media. 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

PPA0465/498/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd February 2023

10 DATE OF REVISION OF THE TEXT