

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Soolantra 10mg/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 pale yellow hydrophilic cream.

## 4 CLINICAL PARTICULARS

As per PA0590/028/001

## 5 PHARMACOLOGICAL PROPERTIES

As per PA0590/028/001

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Glycerol  
Isopropyl palmitate  
Carbomer  
Dimeticone  
Disodium 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

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### **6.3 Shelf life**

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 30 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**

Lexon Pharmaceuticals (Ireland) Limited  
Block 3  
Harcourt Centre  
Harcourt Road  
Dublin 2  
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## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23176/014/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 20<sup>th</sup> October 2017

## **10 DATE OF REVISION OF THE TEXT**

October 2021