

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rozex 7.5 mg/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Metronidazole 0.75% w/w (7.5mg/g)

Excipients with known effect:
Cetostearyl alcohol

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
Product imported from the Czech Republic:
White to slightly beige shiny cream.

4 CLINICAL PARTICULARS

As per PA0590/010/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0590/010/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Emulsifying wax (cetostearyl alcohol including cetyl alcohol and stearyl alcohol)
Benzyl alcohol
Isopropyl palmitate
Glycerol
Sorbitol 70% (non-crystallising)
Lactic acid and/or sodium hydroxide (for pH adjustment)
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 tube and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze.

6.5 Nature and contents of container

Aluminium tube in a carton.

Pack size: 30g

6.6 Special precautions for disposal and other handling

Replace cap tightly after use.

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

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/222/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd June 2017

10 DATE OF REVISION OF THE TEXT

July 2018