

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rozex 7.5 mg/g Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of gel contains 7.5mg metronidazole equivalent to metronidazole 0.75% w/w.

Excipients with known effect:

Propyleneglycol, Propyl parahydroxybenzoates (E216), Methylparahydroxybenzoates (E218)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel

Product imported from Spain:

A clear colourless to light yellow viscous single phase gel.

Product imported from Greece:

Colourless to yellowish gel, which over time can become slightly brown.

4 CLINICAL PARTICULARS

As per PA22743/013/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22743/013/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer 940
Disodium Edetate
Methylparahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Propyleneglycol
Sodium hydroxide (for pH-adjustment)
Purified water

Product imported from Greece contains:

Carbomer 980
Disodium Edetate
Methylparahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Propyleneglycol
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 container 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 freeze.

6.5 Nature and contents of container

Aluminium tube in a carton or an over-labelled carton.

Pack size: 30g

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

PPA0465/222/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 4th September 2009

10 DATE OF REVISION OF THE TEXT

September 2022