

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: Propylene glycol (E1520)

Propyl parahydroxybenzoate (E216)

Methyl parahydroxybenzoate (E218)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel

Product imported from *Greece*

Colourless to pale yellow homogenous gel which may turn to slightly brown colour over time.

4 CLINICAL PARTICULARS

As per PA22743/013/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22743/013/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbopol 980

Disodium edetate

Methyl parahydroxybenzoate (E218)

Propyl parahydroxybenzoate (E216)

Propylene glycol (E1520)

Sodium hydroxide (for pH-adjustment)

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be 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 freeze.

6.5 Nature and contents of container

Aluminium tubes; pack size: 30 g.

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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
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Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/184/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 17th September 2021

10 DATE OF REVISION OF THE TEXT