

# 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  
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

Carbomer 940 (Carbopol 980)  
Disodium edetate  
Methyl parahydroxybenzoate (E218)  
Propyl parahydroxybenzoate (E216)  
Propylene glycol  
Sodium hydroxide  
Purified water

### 6.2 Incompatibilities

Not applicable.

### 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.

#### **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 sizes: 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**

Lexon Pharmaceuticals (Ireland) Limited  
Block 3  
Harcourt Centre  
Harcourt Road  
Dublin 2  
Ireland

### **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA23176/011/001

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

Date of first authorisation: 7<sup>th</sup> July 2017

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

November 2022