

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nizoral 20 mg/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ketoconazole 2% w/w (each gram of cream contains 20mg).

Excipients with known effect:

propylene glycol,
stearyl alcohol,
cetyl alcohol.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from Romania

White odourless cream

4 CLINICAL PARTICULARS

As per PA0330/041/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0330/041/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

purified water,
propylene glycol
cetyl alcohol,
stearyl alcohol,
sorbitan monostearate,
polysorbate 60 and 80
sulfite anhydrous sodium (E221)
isopropyl myristate

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

6.5 Nature and contents of container

A lined aluminium tube, with a screw cap, containing 2 x15g of cream

6.6 Special precautions for disposal and other handling

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th June 2017

10 DATE OF REVISION OF THE TEXT

February 2022