

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nizoral Dandruff 20mg/g Shampoo

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains 20 mg of ketoconazole.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Shampoo

Product imported from Belgium and the UK:

Pink, viscous shampoo.

4 CLINICAL PARTICULARS

As per PA0823/052/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0823/052/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium lauril ether sulfate,
Disodium monolauryl ether sulphosuccinate,
Coconut fatty acid diethanolamide,
Laurdimonium hydrolysed animal collagen,
Macrogol 120 methyl glucose dioleate,
Sodium chloride,
Sodium hydroxide,
Imidurea,
Hydrochloric acid,
Erythrosine (E127)
Purified water

Product imported from Belgium also contains perfume mix

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be 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.

6.5 Nature and contents of container

Plastic bottles containing 60ml, 100ml or 120ml. Enclosed in a cardboard carton.

Not all pack sizes may be marketed

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/042/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 May 1996

Date of last renewal: 20 May 2006

10 DATE OF REVISION OF THE TEXT

July 2016