Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Gyno-Daktarin 20mg/g vaginal cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Miconazole nitrate 2% w/w
Each gram of cream contains 20 mg miconazole nitrate.
Excipients: Contains benzoic acid and butylated hydroxyanisole.
For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Vaginal cream.

Product imported from Greece:
The cream is white and homogeneous.

4 CLINICAL PARTICULARS

As per PA0748/020/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0748/020/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tefose
Labrafil
Mineral oil
Benzoic acid (E210)
Butylated hydroxyanisole (E320)
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.

6.5 Nature and contents of container

Tube containing 78g of cream.
The cream is supplied with disposable cardboard vaginal applicators.

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

PPA0465/291/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th July 2012

10 DATE OF REVISION OF THE TEXT

January 2015