

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dalacin 2 % Vaginal Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains clindamycin phosphate equivalent to 20 mg or 2.0 % w/w clindamycin.

Each applicator full of 5 grams of vaginal cream contains approximately 100 mg of clindamycin phosphate

Excipients with known effect:

Propylene glycol

Cetostearyl alcohol

Benzyl alcohol

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Vaginal cream.

Product imported from the Czech Republic and Greece:

White, semi-solid cream.

4 CLINICAL PARTICULARS

As per PA0822/119/002

5 PHARMACOLOGICAL PROPERTIES

As per PA0822/119/002

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitan stearate (Type I)

Polysorbate 60

Propylene glycol (E1520)

Stearic acid

Cetostearyl alcohol

Cetyl palmitate

Mineral oil (viscosity 180)

Benzyl alcohol (E1519)

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 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. Do not freeze.

6.5 Nature and contents of container

Tube with cap containing 40 gram of cream. Each pack contains one tube of cream and seven vaginal applicators in a plastic canister.

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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/416/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th December 2015

10 DATE OF REVISION OF THE TEXT

May 2025