

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Acnecide 5% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrous benzoyl peroxide equivalent to benzoyl peroxide 5 % w/w.

Excipient(s) with known effect:

One gram of gel contains 40 mg of propylene glycol (E1520)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel

Product imported from Austria

White to off-white, smooth gel.

4 CLINICAL PARTICULARS

As per PA22743/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA22743/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Docusate sodium
sodium edetate
Poloxamer
Carbomer
Propylene glycol
methacrylate copolymer
Glycerol
Silicon dioxide
Purified Water
Sodium hydroxide to adjust the Ph

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.

Shelf life after opening: 6 months

6.4 Special precautions for storage

Do not store above 25°C.

Do not freeze.

6.5 Nature and contents of container

White low density polyethylene tubes with white polypropylene screw caps. Pack size 60 g (2 x 30 g)

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

PPA23176/054/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th October 2022

10 DATE OF REVISION OF THE TEXT