

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Exterol 5% w/w Ear Drops, Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Urea hydrogen peroxide 5.0% w/w.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ear drops, solution (Ear drops)

Product imported from the UK

Clear, straw-coloured, viscous solution.

4 CLINICAL PARTICULARS

As per PA0278/009/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0278/009/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

8-hydroxyquinoline
Glycerol

6.2 Incompatibilities

Do not use concurrently with anything else in the ear.

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the bottle and outer package of the product on the market in the country of origin.

Discard 4 weeks after first opening.

6.4 Special precautions for storage

Store upright. Do not store above 25°C.

Keep the bottle tightly closed. Keep the bottle in the outer carton.

6.5 Nature and contents of container

Plastic bottle, with nozzle applicator and tamper-evident screw cap, containing 8 ml.

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

Lexon (UK) Ltd
Unit 18
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Worcestershire B98 0RE
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1097/044/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th February 2018

10 DATE OF REVISION OF THE TEXT