

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Alphagan 0.2% w/v (2 mg/ml) eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml solution contains 2.0 mg brimonidine tartrate, equivalent to 1.3 mg of brimonidine.

Excipient with known effect

Benzalkonium chloride

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Product imported from Spain

Clear, greenish-yellow to light greenish-yellow solution.

4 CLINICAL PARTICULARS

As per PA0148/006/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0148/006/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Poly (vinyl alcohol)
Sodium chloride
Sodium citrate
Citric acid monohydrate
Purified water
Sodium hydroxide or hydrochloric acid for pH adjustment

6.2 Incompatibilities

Not applicable.

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.

After first opening use within 28 days.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Plastic bottle containing 5ml of eye drop solution.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Lexon Pharmaceuticals (Ireland) Limited
Block 3
Harcourt Centre
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA23176/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31st March 2017

10 DATE OF REVISION OF THE TEXT

February 2022