

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(s) with known effect:

Contains benzalkonium chloride

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Product imported from the Czech Republic, Netherlands and Poland:

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

4 CLINICAL PARTICULARS

As per PA1824/007/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1824/007/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride

Poly(vinyl alcohol)

Sodium chloride

Sodium citrate

Citric acid monohydrate

Purified water

Hydrochloric acid (for pH-adjustment) or Sodium hydroxide for (pH-adjustment)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product shall be the date shown on the container and outer carton of the product as marketed 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

White dropper bottles with a tip. The cap is either a conventional polystyrene screw cap or a Compliance Cap (C-Cap). One 5 ml bottle in a cardboard carton.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/413/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st July 2015

10 DATE OF REVISION OF THE TEXT

December 2022