

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

Contains benzalkonium chloride

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye drops, solution.

Product imported from Belgium:

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.

One 5 ml bottle in a cardboard carton.

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

IMED Healthcare Ltd.,
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/252/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th November 2025

10 DATE OF REVISION OF THE TEXT