Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

COSOPT 20 mg/ml + 5 mg/ml eye drops, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 22.26 mg of dorzolamide hydrochloride corresponding to 20 mg dorzolamide and 6.83 mg of timolol maleate corresponding to 5 mg timolol.

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 Greece
Clear, colourless to nearly colourless, slightly viscous solution with a pH between 5.5 and 5.8 and an osmolarity of 242-323 mOsM.

4 CLINICAL PARTICULARS

As per PA0879/005/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0879/005/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Hydroxyethyl cellulose
Mannitol (E421)
Sodium citrate (E331)
Sodium hydroxide (E524) for pH adjustment
Water for injections

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the container and outer carton of the product on the market in the country of origin.

COSOPT should be used no longer than 28 days after first opening the container.

6.4 Special precautions for storage

This medicinal product does not require any special temperature storage conditions.
Keep the bottle in the outer carton, in order to protect from light.

6.5 Nature and contents of container

The COSOPT container contains 5 ml of solution.
White translucent low-density polyethylene container, a transparent dropper and a white cap.
Tamper evidence is provided by a safety strip on the container label.

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

PPA1463/060/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th April 2012

10 DATE OF REVISION OF THE TEXT

March 2023