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(s) with known effect: benzalkonium chloride

For the full list of the excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Product imported from France, Italy, Greece and Romania:
Clear, colourless or 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 (E 421)
Sodium citrate (E 331)
Sodium hydroxide for pH adjustment
Water for injections

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 package 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 container in the outer carton in order to protect from light.

6.5 Nature and contents of container

Two alternate containers may be marketed.
White translucent plastic container, a dropper and a white screw cap. One container contains 5 ml of solution.
or
The OCUMETER Plus Ophthalmic Dispenser consists of a translucent container with a sealed dropper tip, a flexible fluted side area which is depressed to dispense the drops, and a 2-piece cap assembly. One dispenser unit containing 5 ml in a cardboard carton.
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

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/296/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

August 2012
August 2014
January 2019
Last updated: April 2021

10 DATE OF REVISION OF THE TEXT

January 2024