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.

Excipients: Benzalkonium chloride 0.075 mg/ml

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution

Product imported from the Italy:
Clear, colourless to nearly colourless, slightly viscous solution.

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
Sodium citrate
Sodium hydroxide
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 as marketed 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 OCUMETER Plus Ophthalmic Dispenser consists of a translucent, high-density polyethylene container with a sealed dropper tip, a flexible fluted side area which is depressed to dispense the drops, and a 2-piece cap assembly. The 2-piece cap mechanism punctures the sealed dropper tip upon initial use, then locks together to provide a single cap during the usage period.

Tamper evidence is provided by a safety strip on the container label.

Pack size: 1 x 5ml (single 5ml container)

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

Imbat Limited
Unit L2, North Ring Business Park
Santry
Dublin 9
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/159/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd September 2011

10 DATE OF REVISION OF THE TEXT

March 2018