Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Taptiqom 15 micrograms/ml + 5 mg/ml eye drops, solution in single-dose container

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml solution contains: tafluprost 15 micrograms and timolol (as maleate) 5 mg.

One single-dose container (0.3 ml) of eye drops, solution, contains 4.5 micrograms of tafluprost and 1.5 mg of timolol.

One drop (about 30 microl) contains about 0.45 micrograms of tafluprost and 0.15 mg of timolol.

Excipient with known effect: phosphates.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Product imported from the Netherlands and Greece:
Eye drops, solution in single-dose container (eye drops).

A clear, colourless solution with a pH of 6.0-6.7 and an osmolality of 290-370 mOsm/kg.

4 CLINICAL PARTICULARS

As per PA0879/003/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0879/003/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Disodium phosphate dodecahydrate
Disodium edetate
Polysorbate 80
Hydrochloric acid and/or 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.

After first opening a foil pouch: 28 days.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).
After opening the foil pouch:
- Keep the single-dose containers in the original foil pouch in order to protect from light
- Do not store above 25°C
- Discard an opened single-dose container with any remaining solution immediately after use.

6.5 Nature and contents of container

Low-density polyethylene (LDPE) single-dose containers packed in a foil pouch made of a paper-coated, aluminium-polyethylene laminate. Each single-dose container has a fill volume of 0.3 ml and there are 10 containers in each foil pouch.
Pack of 30 x 0.3 ml single-dose containers in outer carton.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/475/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th June 2021

10 DATE OF REVISION OF THE TEXT

July 2024