

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Saflutan 15 micrograms/ml, eye drops solution, single-dose container

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml of eye drops, solution, contains 15 micrograms of tafluprost.

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

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution, single-dose container (eye drops).

Product imported from Italy and Poland:

A clear, colourless solution.

4 CLINICAL PARTICULARS

As per PA0879/006/001

5 PHARMACOLOGICAL PROPERTIES

As per PA0879/006/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Sodium dihydrogen phosphate dihydrate
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
- 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

Single-dose containers packed in foil pouch. Each single-dose container has a fill volume of 0.3 ml and there are 10 containers in each foil pouch, i.e. 30 x 0.3 ml single-dose containers in each 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
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/324/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th November 2013

10 DATE OF REVISION OF THE TEXT

May 2016