

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dexafree 1 mg/ml eye drops, solution in single dose container

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml solution contains 1 mg of dexamethasone phosphate as dexamethasone sodium phosphate.

Excipient(s) with known effect: Disodium phosphate dodecahydrate

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye drops, solution.

Product imported from France

Clear, colourless to slightly brown solution.

4 CLINICAL PARTICULARS

As per PA1107/005/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1107/005/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate

Disodium phosphate dodecahydrate

Sodium chloride

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 of the sachet: use the single-dose containers within 15 days.

After opening of the single-dose container: use immediately and discard the single-dose container after use.

6.4 Special precautions for storage

Keep the single-dose containers in the sachet, in order to protect from light.

6.5 Nature and contents of container

0.4 ml in single-dose container packed in sachets; box of 30 single-dose containers.

6.6 Special precautions for disposal

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/193/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of authorisation: 20th May 2022

10 DATE OF REVISION OF THE TEXT