Public Summary

Summary for ARTG Entry:	407824 RESTASIS
ARTG entry for	Medicine Listed (Export Only)
Sponsor	Abbvie Pty Ltd
Postal Address	Locked Bag 5029, BOTANY, NSW, 1455 Australia
ARTG Start Date	18/04/2023
Product Category	Medicine
Status	Active
Approval Area	Export only Medicines

Conditions

Except where the sponsor has been contracted by an overseas partry to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products

1 . RESTASIS

Product Type	Single Medicine Product	**Effective Date**	18/04/2023

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Restasis is indicated to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca. Increased tear production was not seen in patients currently taking topical anti-inflammatory drugs or using punctal plugs.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 .

Dosage Form	Eye Drops
Route of Administration	Ophthalmic
Visual Identification	RESTASIS appears as a white opaque to slightly translucent homogenous emulsion.

Active Ingredients

ciclosporin	**.5 mg/g**

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Other Ingredients (Excipients)

carbomer copolymer (type A)

Castor Oil

glycerol

polysorbate 80

purified water

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