ikervis®
ciclosporin 1mg/ml
ONE DROP. ONCE DAILY.

PBS Authority Quick Reference Guide

Ikervis Indication: Severe keratitis in an adult patient with dry eye disease which has not improved despite treatment with tear substitutes.[1]

INITIAL TREATMENT PHASE[2]

Initiation
Initial treatment for up to the first 180 days of treatment with Ikervis

↓

Corneal Fluorescein Staining (CFS)
Patient must have a CFS grade of 4 at treatment initiation using the Oxford scale or equivalent

+

Ocular Surface Disease Index (OSDI)
Patient must have an OSDI score of ≥23 at treatment initiation

+

Artificial Tear (AT) substitutes
- The condition must be inadequately controlled by monotherapy with a preservative free AT substitute; AND
- Patient must be undergoing simultaneous treatment with a preservative free AT substitute.

CONTINUING TREATMENT PHASE[2]

Continuation
Patient must have received PBS-subsidised treatment with Ikervis for this condition

↓

Corneal Fluorescein Staining (CFS)
Improvement (reduction) in CFS by ≥3 grades from baseline (as measured by the same scale as initiation)

+

Ocular Surface Disease Index (OSDI)
OSDI score has improved by ≥30% compared to value stated at treatment initiation

↓

If YES to all, contact PBS for Authorisation
(see over)

If **NO** to any PBS criteria for initiation and continuing phase; and **YES** to Ikervis® indication →

Private (non-PBS):
Patient is not eligible for PBS. The RRP of Ikervis® is $81.90 as a non-PBS prescription^

^RRP is a guide only and there is no obligation to comply with recommended retail prices, retailers are free to set their own prices.

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How to contact PBS for Authority Required approval

(immediate/real-time assessment)

1800 888 333 (24 hours)

www.servicesaustralia.gov.au/HPOS

Checklist for application

PATIENT INFORMATION

- ☐ Medicare number
- ☐ First and last name
- ☐ Full residential address
- ☐ CFS grade
- ☐ OSDI score

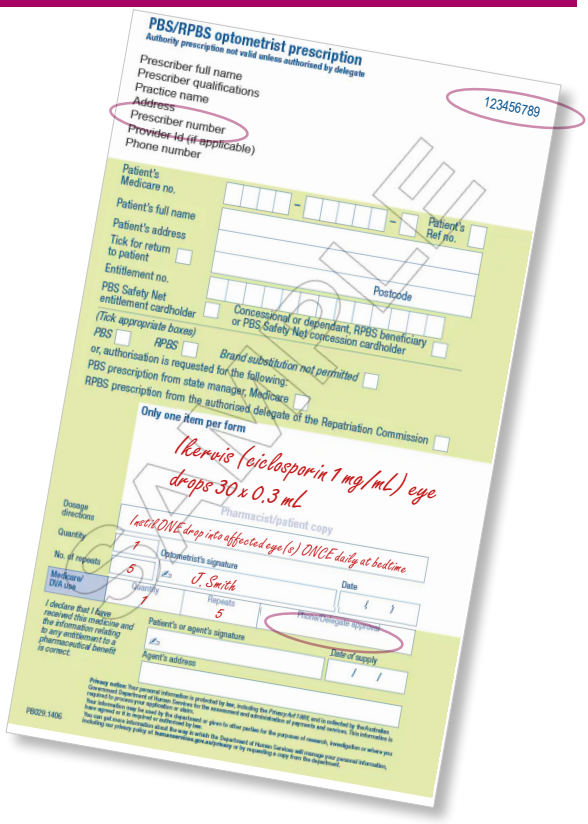
PRESCRIBER INFORMATION

- ☐ Your Prescriber number
- ☐ PBS Authority Prescription Number

IKERVIS INFORMATION

- ☑ PBS item number (12663L)
- ☑ Quantity (30 x 0.3mL units)
- ☑ Number of repeats (max. 5)
- ☑ Ikervis indication

Please see the PBS website for more information


PBS/RPBS optometrist prescription
Authority prescription not valid unless authorised by delegate
Prescriber full name
Prescriber qualifications
Practice name
Address
Prescriber number
Provider Id (if applicable)
Phone number
123456789
Patient's Medicare no.
Patient's full name
Patient's address
Tick for return to patient
Entitlement no.
PBS Safety Net entitlement cardholder
Patient's Ref no.
Postcode
Concessional or dependant, RPBS beneficiary or PBS Safety Net concession cardholder
(Tick appropriate boxes)
PBS
RPBS
Brand substitution not permitted
or, authorisation is requested for the following:
PBS prescription from state manager, Medicare
RPBS prescription from the authorised delegate of the Repatriation Commission
Only one item per form
Ikervis (ciclosporin 1 mg/mL) eye drops 30 x 0.3 mL
Pharmacist/patient copy
Dosage directions
Quantity
No. of repeats
Instil ONE drop into affected eye(s) ONCE daily at bedtime
1
5
Optometrist's signature
J. Smith
Date
Medicare/ DVA Use
Quantity
Repeats
1
5
I declare that I have received this medicine and the information relating to any entitlement to a pharmaceutical benefit is correct.
Patient's or agent's signature
Agent's address
Date of supply
PBS219.1406

PBS Information: Authority Required. Refer to PBS Schedule for full information.

Before prescribing, please review the Approved Product Information available on request to Seqirus Medical Information (1800 642 865) or www.seqirus.com.au/products

▼ This medicinal product is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

MINIMUM PRODUCT INFORMATION: IKERVIS® (ciclosporin 0.1% ophthalmic emulsion) **Indication:** Treatment of severe keratitis in adult patients with dry eye disease which has not improved despite treatment with tear substitutes. **Contraindications**: Hypersensitivity to the active substance or any of the excipients; Ocular or peri-ocular malignancies or premalignant conditions; Active or suspected ocular or peri-ocular infection. **Precautions:** Any reversible underlying conditions, not associated with dry eye disease, should be treated prior to initiating IKERVIS®; History of ocular herpes; Contact lenses should be removed before instillation of eye drops and re-inserted at wake-up time and careful monitoring of severe keratitis is recommended; Glaucoma – limited experience with IKERVIS®. Exercise caution especially with concomitant beta-blockers; Co-administration with eye drops containing corticosteroids may potentiate effects of IKERVIS® on the immune system; May affect host defences against local infection and malignancies. **Use in Pregnancy (Category C):** No data available; Not recommended in pregnancy unless the potential benefit to mother outweighs the potential risk to fetus. **Use in Lactation:** Insufficient information on breastfed infants; it is unlikely that sufficient amounts are present in breast milk. A decision must be made to discontinue either IKERVIS® or breastfeeding during treatment. **Use in Children:** No data available. **Interactions with other medicines:** No data available. **Adverse Effects:** Common: erythema of eyelid; lacrimation increased; ocular hyperaemia; vision blurred; eyelid oedema; conjunctival hyperaemia; eye pruritus. Very common: eye pain, eye irritation. **Dosage and administration:** The recommended dose is one drop of IKERVIS® once daily to be applied to the affected eye(s) at bedtime.

References: 1. Ikervis Product Information. **2.** Pharmaceutical Benefits Scheme (https://www.pbs.gov.au).

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