SCHEDULING STATUS

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1 NAME OF THE MEDICINE

SPERSATEAR, 0,3 % *w/v* eye drops

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each millilitre contains 3 mg of hypromellose.

Excipient(s) with known effect:

Each millilitre contains 0,1 mg benzalkonium chloride (0,01 % *w/v*) as preservative.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Eye drops, solution.

Clear, colourless aqueous solution, slightly viscous.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

An artificial tear. For mucin and aqueous deficient dry eye conditions.

4.2 Posology and method of administration

Posology

Two drops three times a day into each eye or as required.

Method of administration

For ocular use only.

4.3 Contraindications

Hypersensitivity to hypromellose or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

May cause transient mild stinging or temporary blurred vision. If irritation persists or worsens, headache, eye pain, vision changes or continuous redness occur, patients should discontinue use and consult a doctor or pharmacist (see section 4.8).

In order to preserve the sterility, the dropper should not be allowed to touch any part of the eye or any other surface.

SPERSATEAR contains 0,1 mg/ml benzalkonium chloride as preservative which may be deposited in soft contact lenses. Hence, SPERSATEAR should not be used while wearing these lenses. The lenses should be removed before instillation of the drops and not reinserted earlier than 15 minutes after use.

Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised. Patients should be monitored in case of prolonged use.

SPERSATEAR is not intended as a vehicle for other medicines.

SPERSATEAR contains boric acid - Do not give to a child less than 2 years old as this medicine contains boron and may impair fertility in the future.

4.5 Interaction with other medicines and other forms of interaction

Hypromellose prolongs the contact time of topically applied medicines commonly used in ophthalmology.

4.6 Fertility, pregnancy and lactation

Fertility

Studies have not been performed to evaluate the effect of topical ocular administration of hypromellose on fertility.

Hypromellose is a pharmacologically inert compound, and it would not be expected to have any effect on fertility.

Pregnancy

There are no or limited amount of data from the use of ophthalmic hypromellose in pregnant women. Systemic exposure to hypromellose following topical ocular administration is negligible and the product

has no pharmacological properties.

Breastfeeding

It is unknown whether topical hypromellose/metabolites are excreted in human milk. No effects on the breastfed new-born/infant are anticipated since the systemic exposure of the breastfeeding woman to hypromellose is negligible. In addition to this, hypromellose is pharmacologically inert.

4.7 Effects on ability to drive and use machines

May cause blurring of vision on instillation. Do not drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects

System Organ Class	Frequency	Adverse event
Eye disorders	Not known	transient mild stinging or blurred vision, eye pain, foreign body sensation in eyes, eye irritation, ocular hyperaemia

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Due to the characteristics of this preparation, no toxic effects are to be expected with an ocular overdose of SPERSATEAR, nor in the event of accidental ingestion of the contents of one bottle.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A. 15.4 Ophthalmic preparations – others.

Pharmacotherapeutic group: Artificial tears and other indifferent preparations. ATC code: S01XA20.

SPERSATEAR is a corneal wetting agent.

5.2 Pharmacokinetic properties

Hypromellose is an inert substance. It has no pharmacological activity and is not absorbed systemically.

Hence, the pharmacokinetic properties have not been studied.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Borax

Boric acid

Potassium chloride

Sodium chloride

Benzalkonium chloride

Water for injection

Hydrochloride acid (for pH-adjustment)

Sodium hydroxide (for pH-adjustment)

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months unopened.

DO NOT USE FOR MORE THAN 30 DAYS AFTER OPENING.

6.4 Special precautions for storage

Store in cool place, at or below 30 °C. Protect from light.

6.5 Nature and contents of container

20 ml plastic dropper bottle with tamper evident plastic screw cap.

6.6 Special precautions for disposal and other handling

Do not touch dropper tip to any surface as this may contaminate the contents (see section 4.4).

7 HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road

Erand Gardens,

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

8 REGISTRATION NUMBER

N/15.4/22

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17 February 1984

10 DATE OF REVISION OF THE TEXT

01 March 2022

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