AUSTRALIAN PRODUCT INFORMATION

EYEZEP®

Azelastine (as hydrochloride) eye drops

1 NAME OF THE MEDICINE

Azelastine hydrochloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

EYEZEP eye drops contain 0.5 mg/mL azelastine hydrochloride as the active ingredient (equivalent to 0.457 mg/mL azelastine base). EYEZEP eye drops also contains 0.125 mg/mL of benzalkonium chloride and 0.5 mg/mL of disodium edetate as antimicrobial preservatives.

For the full list of excipients, see **Section 6.1 List of excipients**.

3 PHARMACEUTICAL FORM

EYEZEP (azelastine hydrochloride) eye drops is a clear, colourless, isotonic aqueous solution with a pH of 5.5-6.5.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Treatment and prevention of the symptoms of seasonal and non-seasonal (perennial) allergic conjunctivitis in adults and children 4 years and older.

4.2 DOSE AND METHOD OF ADMINISTRATION

Seasonal allergic conjunctivitis:

The usual dosage in adults and children 4 years and older is one drop in each eye twice daily that can be increased, if necessary to four times daily. If allergen exposure is anticipated EYEZEP eye drops should be administered prophylactically, prior to exposure.

Non-seasonal (perennial) allergic conjunctivitis:

The usual dosage in adults and children 4 years and older is one drop in each eye twice daily that can be increased, if necessary to four times daily. As safety and efficacy have been demonstrated in clinical trials for a period of up to 6 weeks, the duration of any course should be limited to a maximum of 6 weeks.

4.3 CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The preservative in EYEZEP eye drops, benzalkonium chloride, may cause eye irritation and discolour soft contact lenses. Where appropriate, contact lenses should be removed before application of the eye drops and not replaced for at least 15 minutes following application.

EYEZEP eye drops are not intended for treatment of eye infections.

Use in renal and hepatic impairment

In a single oral dose study in 9 patients, renal insufficiency (creatinine clearance <50 mL/min) resulted in a 70-75% higher C_{max} and AUC compared to normal subjects. However, the number of patients evaluated in this study is too small to draw meaningful conclusions.

No information regarding the use of EYEZEP eye drops in renally impaired patients is available.

Use in the elderly

A pharmacokinetic study in elderly patients (n=15) receiving oral azelastine hydrochloride 4.4 mg twice daily found a prolongation of the t_{max} and an increase in C_{max}, and AUC compared to results in healthy volunteers. This can be attributed to the age-related changes in physiological functions. There have been no specific studies in the elderly with the eye drops.

While these should be respected for orally administered azelastine, similar considerations are not deemed necessary for the eye drops due to the very low total levels of systemic absorption following this route of administration.

Paediatric use

The use of EYEZEP eye drops can be recommended in children 4 years and older suffering from seasonal or non-seasonal (perennial) allergic conjunctivitis.

The efficacy and safety of EYEZEP eye drops in children under 4 years of age has not been established.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No specific interactions have been studied with EYEZEP eye drops. Interaction studies at high oral doses of azelastine hydrochloride have been performed, however, they bear no relevance to the eye drop formulation as systemic levels would be in the picogram range.

After oral administration of 4.4 mg azelastine hydrochloride twice daily, cimetidine has been shown to increase the plasma levels of azelastine. This is thought to be due to cimetidine inhibiting the metabolism of azelastine by interacting with the hepatic cytochrome P450 system. No interaction was seen following co-medication with ranitidine.

No significant pharmacokinetic interaction was observed with the co-administration of an oral 4.4 mg dose of azelastine hydrochloride twice daily and theophylline 300 mg or 400 mg twice daily.

Interaction studies investigating the cardiac repolarisation effects of concomitantly administered oral azelastine hydrochloride (4.4 mg bd) and erythromycin (500 mg tid) or ketoconazole (200 mg bd) were conducted. Oral erythromycin had no effect on azelastine pharmacokinetics or QTc based on analysis of serial electrocardiograms. Ketoconazole interfered with the measurement of azelastine plasma levels; however, no effects on QTc were observed.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on Fertility

Azelastine demonstrated no carcinogenic potential in mice and rats at dietary doses up to 25 and 30 mg/kg/day respectively. Azelastine demonstrated no genotoxic potential in standard assays for gene mutations, chromosomal damage and DNA damage. In male and female rats, azelastine at oral doses of 30 mg/kg/day and greater (over 3 orders of magnitude higher than the maximum recommended clinical dose on body surface area basis) caused a

decrease in the fertility index, but in long-term toxicity studies up to two years there were no drug related alterations in reproductive organs either in males or in females in this species. A clinical study in 21 healthy human females using an intranasal dose of 1.12 mg/day azelastine found no effect on ovulation or sexual hormone pattern.

Use in Pregnancy (Category B3)

In pregnant rats there was evidence of significant diaplacental transfer of the drug to the foetuses. Azelastine was embryolethal and teratogenic in mice at oral doses greater than 30 mg/kg/day. In rats, azelastine was embryotoxic at oral doses greater

than 3 mg/kg/day, and teratogenicity and embryolethality were seen at doses greater than 30 mg/kg/day. In rabbits, azelastine was teratogenic at oral doses greater than 20 mg/kg/day. In pregnant rats, azelastine demonstrated no perinatal/postnatal toxicity at oral doses up to 30 mg/kg/day.

In rats, the no effect doses resulted in plasma levels which were at least 50 times the plasma levels at the maximum recommended ocular dose in humans (The calculation of the safety factor is based on plasma levels derived from oral subchronic toxicity studies).

There are no adequate and well-controlled clinical studies in pregnant women. EYEZEP eye drops should be used during pregnancy only if the benefit to the mother justifies the potential risk to the foetus.

Australian categorisation definition of: Category B3: Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human foetus having been observed. Studies in animals have shown evidence of an increased occurrence of foetal damage, the significance of which is considered uncertain in humans.

Use in Lactation

In lactating rats approximately 0.2% of a 10 mg/kg oral dose of ^{14}C-azelastine was transferred to the maternal milk. A perinatal/postnatal study in rats showed no adverse effect at oral doses up to 30 mg/kg/day. No data are available in humans. Azelastine should not be used in breastfeeding women unless the expected benefits outweigh the risks to the feeding infant.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Due to the low systemic exposure, no influence is expected. Patients with seasonal allergic conjunctivitis are likely to experience watery and itchy eyes which may affect vision. The mild, transient irritation that may be experienced after application of EYEZEP eye drops is unlikely to affect vision to any greater extent. However, if there are any transient effects on vision, the patient should be advised to wait until this clears before driving or operating machinery.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

EYEZEP eye drops are generally well tolerated. In the following the most frequent adverse drug reactions with the recommended dosage reported in clinical trials and from post marketing reporting are presented.

Commonly (1.0-10%), a mild, transient irritation (burning or stinging) in the eye on instillation of EYEZEP eye drops is experienced. Less frequently reported is a bitter taste. In very rare cases allergic reactions may occur.

Frequency of adverse reactions experienced:

Immune system disorders	***Very rare*** *(1/10,000)*	Allergic reaction
Nervous system disorders	***Uncommon*** *(≥ 1/1,000 and <1/100)*	Taste bitter
Eye disorders	***Common***	Eye irritation

	(≥ 1/100 and < 1/10)	

Clinical Trial Data

The following table shows adverse events/adverse drug reactions reported in clinical trials with EYEZEP eye drops with an incidence of >0.5%, irrespective of a causal relationship to the administration of the drug. A total of 739 patients were exposed to EYEZEP eye drops and 606 patients were exposed to placebo.

System Organ Class	Adverse Events Relative Incidence (EYEZEP-Placebo) %	Adverse Drug Reactions* Relative Incidence (EYEZEP-Placebo) %
Global Incidence	**19.9**	**22.5**
Eye Disorders		
Eye irritation (burning, stinging)	19.1	18.4
Conjunctivitis	0.7	1.0
Eye pain	0.7	0.5
Nervous System Disorders		
Taste perversion	8.5	8.0
Headache	1.8	-0.4
Dizziness	0.5	0.2
Respiratory, Thoracic and Mediastinal disorders		
Coughing	2.0	-0.1
Dyspnoea	1.7	-
Rhinitis	2.0	0.1
Upper respiratory tract infection	0.5	-
Gastrointestinal Disorders		
Nausea	0.7	-
Cardiac Disorders		
Angina pectoris	0.5	-
General Disorders and Administration Site Conditions		
Fatigue	0.5	0.1
*ADRs defined as adverse events with at least a possible relationship to study medications.		

Reporting Suspected Adverse Effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

No specific reactions after ocular overdosage are known, and with the ocular route of administration, overdosage reactions are not anticipated.

In the event of overdosage after accidental oral uptake the signs and symptoms which may be anticipated in humans include drowsiness, confusion, coma, tachycardia and hypotension. Symptomatic and supportive treatment should be instigated as there is no known antidote.

For information on the management of overdose, contact the Poison Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of Action

Azelastine hydrochloride, a phthalazinone derivative, is a potent antiallergic compound with histamine H1-receptor antagonist activity and a rapid onset (within 10 to 20 minutes) and long duration (up to 12 hours) of action (for details see experimental studies below). The major metabolite, desmethylazelastine, also exhibits H1-receptor antagonist activity.

EYEZEP eye drops are administered as a racemic mixture. The racemate, R- and S- enantiomers were equally potent at inhibiting eyelid histamine-induced oedema in rats, however the R-enantiomer was 2-fold less active at inhibiting eyeball histamine-induced oedema. In several ocular allergy models azelastine hydrochloride in physiological saline or as an eye drop formulation proved to be effective.

Data from in vivo (preclinical) and in vitro studies show that azelastine inhibits the synthesis or release of the chemical mediators known to be involved in early and late stage allergic reactions, e.g. histamine and leukotriene.

In early phase studies in humans, EYEZEP eye drops were effective in the symptomatic relief and the prophylaxis of allergen-induced eye symptoms. These studies use an allergen challenge model. In one study where EYEZEP eye drops were administered 20 minutes after conjunctival provocation in 20 asymptomatic patients, relief of symptoms (itching of the eyes, and conjunctival redness, lacrimation and swollen eyelid) occurred 10 to 20 minutes following instillation of EYEZEP eye drops. The symptoms were assessed according to a 4-point rating scale, with a total symptom score range of 0 to 12. The mean of the total symptom score of all patients of these conjunctival symptoms measured 30 minutes after allergen challenge decreased from 8.5 to 4.6 and from 8.5 to 7.7 following EYEZEP eye drops and placebo, respectively. This symptomatic relief of allergen-induced conjunctival symptoms was significantly ($p<0.01$) greater than placebo.

A single dose of EYEZEP eye drops instilled 6 to 9 hours prior to allergen challenge statistically significantly ($p<0.50$) reduced the development of itchy eyes when compared to placebo in 21 asymptomatic patients. In another conjunctival provocation test study involving a total of 32 asymptomatic patients, EYEZEP eye drops protected against allergen-induced conjunctival symptoms (itching of the eyes, conjunctival redness) over a period of up to 12 hours ($p<0.01$).

EYEZEP eye drops also have an effect on the inflammatory process of allergy as defined by a significant decrease in the eosinophilic and neutrophilic infiltration, and ICAM-1 expression during both early and late phase reactions following allergen challenge. Following repeated application of EYEZEP eye drops for a period of 7 days, the sum score of conjunctival symptoms (itching of the eyes, conjunctival redness, lacrimation, swollen eyelids) measured 30 minutes after allergen challenge was significantly ($p<0.01$) lower following azelastine (2.9) pre-treatment compared to placebo (8.3). Furthermore, the increase of inflammatory cells (monocytes, lymphocytes, eosinophils, neutrophils) in conjunctival scrapings was clearly suppressed by azelastine during the early (30 minutes after challenge) as well as the late (6 hours after challenge) allergic reaction.

Clinical Trials

In a number of placebo- and active-controlled clinical studies, EYEZEP eye drops have been shown to be effective in the treatment and prevention of seasonal and non-seasonal (perennial) allergic conjunctivitis, especially for itching of the eye, conjunctival redness, and flow of tears.

<u>Seasonal allergic conjunctivitis:</u>

Five randomised, double-blind, placebo-controlled, confirmatory environmental studies (Study nos. 2981, 2982, 2983, 2984, 2985) were conducted in adult patients. Treatment duration was generally 2 weeks except for one study with a treatment period of 8 weeks (2983). In 4 of the 5 trials, consistent statistically significant superiority

favouring the use of EYEZEP eye drops over placebo was observed. The design of the remaining trial (2984) was shown to be insensitive, as there was no difference between active treatments and placebo.

Improvement Sum Scores "Itching Eyes, Flow of Tears, Conjunctival Redness" (pp analysis; last observation carried forward; means ± SD):						
Study No.	**Drug**	**No. of Patients**	**Score Day 0**	**Score Differences to Day 0 (*5)**		
				Day 3 (*4)	**Day 7**	**Day 14**
2981	EYEZEP	89	6.9 ± 1.0	- 3.8 ± 2.3*	- 4.2 ± 2.2*	- 4.7 ± 2.3*
	LEV	93	7.0 ± 1.1	- 3.2 ± 2.6	- 4.4 ± 2.5**	- 4.5 ± 2.7
	PLA	90	7.0 ± 1.0	- 2.9 ± 2.4	- 3.3 ± 2.5	- 3.8 ± 2.6
2982	EYEZEP	41	6.6 ± 0.8	- 4.5 ± 2.0*	- 4.5 ± 2.0	- 4.3 ± 2.4
	DSCG	47	6.8 ± 1.0	- 4.0 ± 2.0	- 4.2 ± 2.2	- 4.6 ± 2.6
	PLA	48	6.8 ± 1.0	- 3.2 ± 2.6	- 3.8 ± 2.4	- 4.0 ± 2.6
2983 (*1)	EYEZEP	202	6.9 ± 0.9	- 3.4 ± 2.1	_ _ _	- 4.3 ± 2.3**
	PLA	68	7.0 ± 1.1	- 2.8 ± 2.4		- 3.3 ± 2.9
2984	EYEZEP	73	6.7 ± 1.0	- 3.8 ± 2.0		- 4.3 ± 2.5
	LEV	67	6.9 ± 1.1	- 4.5 ± 2.3	_ _ _	- 4.7 ± 2.4
	PLA	73	6.9 ± 1.0	- 3.9 ± 2.1		- 4.5 ± 2.5
2985	EYEZEP	137	7.0 ± 1.0	- 3.3 ± 2.2*	- 4.2 ± 2.3	- 5.4 ± 2.2*
	PLA	139	7.2 ± 1.1	- 2.7 ± 2.3	- 3.8 ± 2.5	- 4.8 ± 2.7
3021 (*2)	EYEZEP	160	6.9 ± 0.9	- 3.8 ± 1.7***		- 5.5 ± 1.8***
	DSCG	79	7.0 ± 1.0	- 3.0 ± 1.9	_ _ _	- 4.5 ± 2.2
	PLA	80	6.9 ± 1.0	- 1.9 ± 2.1		- 3.0 ± 2.7
3034 (*2) (*3)	EYEZEP	47	7.3 ± 1.2	- 4.3 ± 2.3**		- 5.4 ± 2.3**
	LEV	32	7.2 ± 1.0	- 5.1 ± 1.7	_ _ _	- 5.6 ± 2.0
	PLA	28	6.9 ± 1.0	- 2.6 ± 2.6		- 3.4 ± 3.0
3062 (*2)	EYEZEP	95	6.9 ± 1.0	- 4.4 ± 2.1*		- 4.7 ± 2.3
	DSCG	49	6.8 ± 0.9	- 3.8 ± 2.2	_ _ _	- 4.3 ± 2.7
	PLA	46	6.8 ± 0.9	- 3.5 ± 2.2		- 4.7 ± 2.6
(*1): 8-week treatment; unbalanced treatment groups: 3 pat. EYEZEP vs. 1 pat. PLA (*2): unbalanced treatment groups: 2 pat. EYEZEP vs. 1 pat. reference vs. 1 pat. PLA (*3): 4-week treatment (*4): Primary efficacy end-point (*5): 2-sided t-test: *: $p < 0.05$; **: $p < 0.01$; ***: $p < 0.001$						

Three of these studies (2981, 2984, 2982) additionally compared EYEZEP eye drops to either levocabastine (LEV) or disodium cromoglycate (DSCG) eye drops and found the effects of both active substances to be comparable. Long-term safety and efficacy was confirmed in the 8-week study.

Three randomised, double-blind, placebo-controlled environmental studies (3021, 3034, 3062) were performed in children aged 4 to 12 years. Results of these 3 paediatric studies with treatment duration of 2 to 4 weeks were also significantly superior in favour of EYEZEP eye drops and confirm the evidence of efficacy seen in the adult studies. All of these trials additionally compared EYEZEP eye drops to disodium cromoglycate (DSCG) or levocabastine (LEV) and found the effects of both active substances to be at least comparable.

Primary efficacy endpoint in all of these studies was the responder rate on Day 3. Response was defined as a reduction of ≥ 3 score points in the sum of scores of itching eyes, conjunctival redness, flow of tears within 3 days of start of treatment. The responder rates were statistically significantly superior for EYEZEP eye drops compared to placebo in 7 of the 8 studies ($p<0.04$).

Responder Rates of Confirmatory Studies:						
Study No.	**Response Rate Day 3 (Primary)**			**Response Rate Day 14**		
	EYEZEP	**PLA**	**p-value (*2)**	**EYEZEP**	**PLA**	**p-value (*2)**
Adults:						
2981	69%	51%	p=0.02	81%	70%	p=0.14
2982	85%	56%	p<0.01	85%	68%	p=0.12
2983	65%	49%	p=0.02	80%	58%	p<0.01

2984	73%	74%	p=1.00	83%	88%	p=0.456
2985	68%	47%	p<0.01	91%	80%	p=0.02
Children(*1):						
3021	80%	34%	p<0.01	94%	51%	p<0.01
3034	74%	39%	p<0.01	86%	65%	p=0.07
3062	80%	63%	p=0.04	85%	78%	p=0.34
(*1): There were no studies on children less than 4 years or greater than 12 years. (*2): 2-sided exact Fisher test						

The administered dosage of EYEZEP eye drops was one drop/eye BID (total daily dose 0.06 mg) and could be increased to one drop/eye TID to QID (at maximum 0.12 mg/day). In all of these studies, the use of EYEZEP eye drops was shown to be safe and well tolerated.

Non-seasonal (Perennial) allergic conjunctivitis:

Two randomised, double-blind, placebo-controlled environmental trials (3111, 3130) of similar design showed significantly superior effects of EYEZEP eye drops compared to placebo in adults ≥18 years over a treatment duration of 6 weeks. The predominant therapeutic effect in both studies was seen on itching of the eyes and conjunctival redness and was most pronounced by the end of the treatment period. One of the trials (3111) additionally compared EYEZEP eye drops to levocabastine (LEV) and found the effects of both active substances to be comparable.

Improvement of Sum Score "Itching Eyes, Conjunctival Redness" in Non-seasonal (Perennial) Allergic Conjunctivitis (% of Patients):

Study	**Drug**	**Number of Patients**	**Score Improvement up to Day 7 (*2)**		
			Improved	**Improved ≥ 2**	**No Symptoms**
3111 (*1)	EYEZEP	57	86.0	70.2	22.8
	PLA	56	53.6	19.6	3.6
	LEV	26	88.5	50.0	7.7
3130	EYEZEP	58	81.0	55.2	0.0
	PLA	58	44.8	13.8	0.0
			Score improvement up to Week 6 (*2)		
			Improved	**Improved ≥ 2**	**No Symptoms**
3111 (*1)	EYEZEP	57	91.2	80.7	56.1
	PLA	56	67.9	35.7	16.1
	LEV	26	100.0	76.9	57.7
3130	EYEZEP	58	100.0	94.8	46.6
	PLA	58	79.3	32.8	10.3

(*1): unbalanced treatment groups: 2 pat EYEZEP vs. 2 pat. PLA vs. 1 pat. reference
(*2): improved: score reduction of at least 1 point; improved ≥ 2: score reduction of at least 2 points;
no symptoms: Sum Score = 0

In non-seasonal (perennial) allergic conjunctivitis EYEZEP eye drops were administered as one drop/eye BID (total daily dose 0.06 mg). The dosage could be increased to one drop/eye TID to QID (at maximum 0.12 mg/day). Both studies found the use of EYEZEP eye drops to be safe and well tolerated.

Other information

No irritant or sensitising properties of single or repeated applications of EYEZEP eye drops on eye structures were found in studies involving healthy subjects. After topical application of EYEZEP eye drops to healthy subjects and patients with allergic conjunctivitis symptoms, respectively, there was no effect on the intraocular pressure, on the corneal re-epithelisation process, or on tear formation.

No local anaesthetic effect was detected in man by means of a Cochet-Bonnet-Aesthesiometer measuring corneal sensitivity at different time points following single and multiple intraocular administration of EYEZEP eye drops.

5.2 PHARMACOKINETIC PROPERTIES

Following oral administration, azelastine is rapidly absorbed showing an absolute bioavailability of 81% and is distributed predominantly into the periphery. Plasma elimination half-life of azelastine is approximately 20 hours and about 45 hours for the therapeutically active metabolite desmethylazelastine. Excretion occurs mainly via the faeces.

After repeated ocular application of azelastine eye drops (up to one drop in each eye four times daily), Cmax steady state plasma levels of azelastine hydrochloride were very low. Systemic absorption of azelastine following long term administration of eye drops lead to extremely low plasma concentrations of azelastine only and therefore adverse events related to systemic plasma levels of the compound are unlikely to occur.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

Refer to **Section 4.6 – Fertility, Pregnancy and Lactation**

Carcinogenicity

Refer to **Section 4.6 – Fertility, Pregnancy and Lactation**

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

- hypromellose
- disodium edetate
- benzalkonium chloride
- sorbitol solution 70% (crystallising)
- sodium hydroxide
- water for injections

6.2 INCOMPATIBILITIES

Refer to **Section 4.4 – Special warnings and precautions for use** and **Section 4.5 – Interactions with other medicines and other forms of interactions**

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG).

The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30ºC.

EYEZEP eye drops should be discarded 4 weeks after first opening.

6.5 NATURE AND CONTENTS OF CONTAINER

EYEZEP eye drops (AUST R 97489) is available in a 6 mL or 10 mL* screw cap HDPE bottle with dropper.

*not marketed

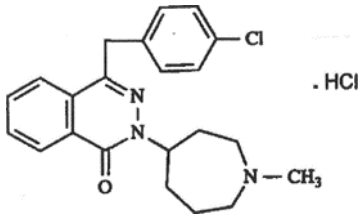
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking it to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Azelastine hydrochloride is chemically (RS)-4-(4-chlorobenzyl)-2-(1-methylazepan-4- yl) phthalazin-1 (2H)-one hydrochloride

Chemical Structure



CAS Number 79307-93-0

The chemical formula is $C_{22}H_{24}OCIN_3$.HCI and its molecular weight is 418.37. It is presented as the racemate.

Azelastine hydrochloride is a white to light beige crystalline, odourless powder. It is freely soluble in chloroform, soluble in ethanol and sparingly soluble in water. It is practically insoluble in ether, n-hexane and toluene.

7 MEDICINE SCHEDULE (POISONS STANDARD)

S2 (Pharmacy Medicine)

8 SPONSOR

Viatris Pty Ltd

Level 1, 30 The Bond

30 – 34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

9 DATE OF FIRST APPROVAL

22 March 2005

10 DATE OF REVISION

27/10/2021

EYEZEP® is a Viatris company trade mark

Summary Table of Changes

Section Changed	Summary of New Information
6.5	Added AUST R number
8	Updated sponsor details

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