PROFESSIONAL INFORMATION

SCHEDULING STATUS:
S2

1. NAME OF THE MEDICINE
GEMINI ® (STERILE EYE DROPS)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:
Each 1 ml contains:

Antazoline HCl	0,5 mg
Tetryzoline HCl	0,4 mg

Excipient with known effect: Preservative: Benzalkonium chloride 0,005% w/v.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Sterile eye drops.
Clear, colourless, odourless solution, free of visible particulate matter.

4. CLINICAL PARTICULARS:
4.1 Therapeutic Indications:
Hayfever,conjunctivitis, allergic conjunctivitis, sore, red or itching eyes.

4.2 Posology and method of administration
Adult: Instil 1 drop, 3 or 4 times daily, into the lower eyelid.
Children 2 – 12 years: Instil 1 drop daily or twice daily.
Contact lenses should be removed before using this medicine. The contact lenses can be placed back 15 minutes afterwards.
Not recommended for children under the age of 2 years.
If redness or irritation continues, gets worse or lasts for more than 3 days consult your doctor.

4.3 Contraindications:

- Hypersensitivity to antazoline HCl, tetryzoline HCl or to any of the excipients of GEMINI STERILE EYE DROPS (see section 6.1).
- Patients with dry eyes, especially keratoconjunctivitis sicca
- Patients at a risk of narrow angle glaucoma.
- Patients receiving monoamine oxidase inhibitors or within 14 days of its treatment.
- Not recommended for children under two years of age, due to the greater incidence of systemic absorption and effects.

4.4 Special warnings and precautions for use
- Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses.
- Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel

abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

- Use with caution in patients with increased intra-ocular pressure, hypertension, cardiac irregularities including heart failure, in patients with poorly controlled hypertension and diabetes mellitus, hyperthyroidism or pheochromocytoma and eye infections.

Other medications should be chosen in case of chronic recurring allergies

4.5 Interaction with other medicines and other forms of interaction

No synergic effect can occur due to the low dose. In cases where another ophthalmic treatment is used, allow an interval of 5 minutes between each administration so as not to wash away the active ingredient.
Preparations containing tetryzoline may not be used in patients receiving MAO inhibitors until 14 days after the last treatment with such active ingredients (increase in blood pressure resulting from the concomitant use of MAO and tricyclic antidepressants).

4.6 Fertility, pregnancy and lactation:

Safety and/or efficacy in pregnancy has not been established.
No controlled studies are available either in animals, pregnant or nursing women.
It is not known whether either active substance of GEMINI STERILE EYE DROPS passes into breast milk.

4.7 Effects on ability to drive and use machines

This medicine may lead to drowsiness, impaired concentration or blurred vision. Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

4.8 Undesirable effects

The undesirable effects listed are based on the MedDRA system organ classes (SOC) classification system. The frequency groupings listed conform to the following convention: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1 000 to <1/100); rare (≥1/10 000 to <1/1 000); very rare (<1/10 000) and unknown (cannot be estimated from the available data)

MeDRA System Organ Class	***Frequency***	***Undesirable effect***
Immune system disorder	Unknown	Hypersensitivity reactions may occur very rarely
Nervous system disorders	Less Frequent	Headache, drowsiness, tremor, and agitation
Eye disorders	Less Frequent	Transient irritation may occur immediately after instillation, blurred vision (after systemic absorption), mydriasis, elevation of intraocular pressure, systemic undesirable effects due to absorption, reactive

		hyperaemia (after discontinuation of the treatment)
Cardiac disorder	Less Frequent	Tachycardia (particularly in small children), Pectanginous symptoms
Vascular Disorders	Less Frequent	Hypertension
Skin and subcutaneous tissue disorders	Less Frequent	Sweating may also occur.

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. Health care 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
Symptoms
After accidental ingestion, especially in children, overdosage is associated with antimuscarinic, extrapyramidal and CNS stimulation and depression. CNS stimulation causes ataxia, excitement, tremors, psychoses, hallucinations, convulsions, hyperexia may also occur. Deepening coma and cardiorespiratory collapse may follow. CNS depression causes drowsiness, coma, convulsions progressing to respiratory failure or possible cardiovascular collapse.
Treatment
In the event of accidental overdosage following oral ingestion, induce vomiting if the patient is still conscious.

5. PHARMACOLOGICAL PROPERTIES
A 15.4 Ophthalmic preparations – other
WHO ATC Code: S01GA52 Tetryzoline/Antazoline

5.1 Pharmacodynamics properties
Antazoline is a H1-antagonist which act by blocking the H1 Histamine receptor through competitive inhibition.
Tetryzoline is a sympathomimetic agent, with alpha adrenergic activity, acts as a local vasoconstrictor.

5.2 Pharmacokinetic properties
None available.

5.3 Preclinical safety data
None available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Benzalkonium chloride
- Hydrochloric Acid 1N
- Hydroxypropyl Methylcellulose
- Sodium chloride
- Water for Injection

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 Months

6.4 Special precautions for storage:

Store in cool place at or below 25 °C.
Discard 30 days after opening.

6.5 Nature and contents of container

20 ml White/Transparent LDPE dropper bottle with dropper insert (LLDPE) and white closure (HDPE).

The 20 ml bottle contains 15 ml solution.

6.6 Special precautions for disposal

Not applicable.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited
1 New Road
Erand Gardens
Midrand, 1685
Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBERS:

H 1254 (Act 101 of 1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06 July 2002

10. DATE OF REVISION OF THE TEXT

21 February 2023

Namibia: NS2 14/15/0397
Botswana: S3 B9323205