

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

GEMINI STERILE EYE DROPS ®

Antazoline Hydrochloride 0,5 mg and Tetryzoline Hydrochloride 0,4mg

Contains benzalkonium chloride 0,05% w/v as a preservative

Read all of this leaflet carefully because it contains important information for you:

GEMINI STERILE EYE DROPS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use GEMINI STERILE EYE DROPS carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share GEMINI STERILE EYE DROPS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet:

1. What GEMINI STERILE EYE DROPS is and what it is used for.
2. What you need to know before you use GEMINI STERILE EYE DROPS
3. How to use GEMINI STERILE EYE DROPS
4. Possible side effects
5. How to store GEMINI STERILE EYE DROPS
6. Contents of the pack and other information

1. What GEMINI STERILE EYE DROPS is and what it is used for:

GEMINI STERILE EYE DROPS is indicated in the topical relief of hayfever conjunctivitis, allergic conjunctivitis, sore, red or itching eyes.

2. What you need to know before you use GEMINI STERILE EYE DROPS

Do not use GEMINI STERILE EYEDROPS if you are/have:

- Allergic to Antazoline or Tetryzoline Hydrochloride or to any of the other ingredients of GEMINI STERILE EYE DROPS (Listed in section 6).
- Dry eyes or inflammation of the eye.
- Narrow-angle glaucoma (a serious eye condition that happens because of changes in the iris, or part of the eye with colour)
- Using *monoamine oxidase inhibitors* (antidepressants) or within 14 days of its treatment.
- Under two years of age.

Warnings and Precautions

Take special care with GEMINI STERILE EYE DROPS:

- You should remove contact lenses before using this medicine and put them back 15 minutes afterwards.
- Use with caution if you have increased eye pressure, hypertension and/or Irregularities with the heart
- If you have constant continuous allergies, please use other medication

Other medicines and GEMINI STERILE EYE DROPS:

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

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 *Monoamine Oxidase 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).

Pregnancy, Breastfeeding & Fertility:

GEMINI STERILE EYE DROPS should not be used in pregnancy. In the absence of sufficient data, the use during lactation is not recommended. No fertility data available. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking GEMINI STERILE EYE DROPS

Driving and using machines:

This medicine may lead to drowsiness, impaired concentration or blurred vision. It is not always possible to predict to what extent GEMINI STERILE EYE DROPS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GEMINI STERILE EYE DROPS affects them.

3. How to use GEMINI STERILE EYE DROPS

Do not share medicines prescribed for you with any other person.

Always use GEMINI STERILE EYE DROPS exactly as described in this leaflet or as your health care professional has told you. Check with your health care professional if you are not sure.

The usual dose is:

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 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.

If you use more GEMINI STERILE EYE DROPS than you should:

Side effects will be precipitated or be of increased severity. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use GEMINI STERILE EYE DROPS:

- Use your next dose at your regular time.
- Do not take a double dose to make up for forgotten individual doses.

4. Possible Side Effects

GEMINI STERILE EYE DROPS can have side effects.

Not all side effects reported for GEMINI STERILE EYEDROPS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GEMINI STERILE EYE DROPS, please consult your health care provider for advice.

Tell your doctor if you notice any of the following side effects:

If any of the following happens, stop taking/ using GEMINI STERILE EYE DROPS and tell your doctor immediately or go to the casualty department at your nearest hospital:

<i>MeDRA System Organ Class</i>	<i>Frequency</i>	<i>Undesirable effect</i>
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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you have any side effects, talk to your health care professional.

You can report side effects to the **Adcock Ingram Pharmacovigilance** department by e-mail to Adcock.Aereports@adcock.com, fax to +27 86 553 0128 or call 011 635 0134.

You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications:
<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of GEMINI STERILE EYEDROPS.

5. How to store GEMINI STERILE EYEDROPS:

Store in cool place at or below 25 °C.

Discard 30 days after opening.

Store all medicines out of reach of children.

Do not use after the expiry date stated on the carton / bottle.

Return all unused medicine to your pharmacist for proper disposal.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What GEMINI STERILE EYE DROPS contains:

Each 1 ml contains:	
Antazoline HCl	0,5 mg
Tetryzoline HCl	0,4 mg

Preservative: Benzalkonium chloride 0,05 % *m/v*

The other ingredients are: Hydrochloric acid 1N, hydroxypropyl methylcellulose, sodium chloride and water for injection.

What GEMINI STERILE EYE DROPS looks like and contents of the pack:

GEMINI STERILE EYE DROPS is a clear, colourless, odourless solution, free of visible particulate matter.

It is packed in 20 ml transparent plastic (LDPE) bottle, fitted with a plastic dropper (LLDPE) of natural colour and a white (HDPE) cap.

Holder of the certificate of registration:

Adcock Ingram Limited

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Midrand, 1685

[Customer Care: 0860 ADCOCK / 232625](tel:0860ADCOCK)

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