Patient Information Leaflet

SCHEDULING STATUS:

S2

GEMINI

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

Contains benzalkonium chloride 0,005% w/v as a preservative

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

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

- Keep this leaflet. You may need to read it again.
- Do not share GEMINI 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 is and what it is used for.
2. What you need to know before you use GEMINI
3. How to use GEMINI
4. Possible side effects
5. How to store GEMINI
6. Contents of the pack and other information

1. What GEMINI is and what it is used for:

GEMINI 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

Do not use GEMINI if you are/have:

- Allergic to Antazoline or Tetryzoline Hydrochloride or to any of the other ingredients of GEMINI (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.

<u>Warnings and Precautions</u>

Take special care with GEMINI:

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

Other medicines and GEMINI:

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 eye 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 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.

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 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 affects them.

3. How to use GEMINI

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

Always use GEMINI 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 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:

- 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 can have side effects.

Not all side effects reported for GEMINI are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GEMINI, 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 and tell your doctor immediately or go to the casualty department at your nearest hospital:

MeDRA System Organ Class	***Frequency***	***Undesirable effect***
Immune system disorder	Unknown	Allergic reactions may occur very rarely
Nervous system disorders	Less Frequent	Headache, drowsiness, shaking movements, and nervousness
Eye disorders	Less Frequent	Transient irritation may occur immediately after using on the eye, blurred vision, widening of the eye, increased pressure in the eye, increase in blood flow (after stopping the treatment)
Cardiac disorder	Less Frequent	Increased heart rate (particularly in small children), Symptoms related to the chest
Vascular Disorders	Less Frequent	High blood pressure
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.

5. How to store GEMINI:

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 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 looks like and contents of the pack:

GEMINI 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.

The 20 ml bottle contains 15 ml solution.

Patient Information Leaflet

Holder of the certificate of registration:

Adcock Ingram Limited
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Customer Care: 0860 ADCOCK / 232625

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