

**PATIENT LEAFLET IN  
ACCORDANCE WITH THE  
PHARMACISTS' REGULATIONS  
(PREPARATIONS) – 1986**

**This medicine is dispensed without  
a doctor's prescription**

## STILLA SINGLES

### Eye drops

#### Composition

##### Each vial contains:

**Tetrahydrozoline HCl 0.05%**

For information about inactive ingredients see section 6 – "Additional information".

**Read the leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

**The medicine is intended for adults and children above 6 years of age. For use in children below this age, refer to a doctor.**

Use this medicine according to the instructions in section 3 – "How should you use the medicine?". Consult the pharmacist if you need more information. Refer to the doctor if the symptoms of the illness worsen or do not improve after 3 days.

#### **1. What is the medicine intended for?**

The medicine is intended for the relief of burning, stinging, irritation and redness in the eyes caused by allergens and irritants such as: smoke, dust, plants and exposure to the sun.

#### **Therapeutic group**

Belongs to the group of sympathomimetic decongestants.

#### **2. Before using the medicine**

##### **Do not use this medicine if:**

You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see details in section 6 – "Additional information").

You suffer from narrow-angle glaucoma. Do not use this medicine in children under two years of age.

##### **Special warnings regarding the use of the medicine**

##### **Before treatment with the medicine, tell the doctor if:**

- You suffer from an infection, the presence of a foreign body, and mechanical or chemical injury of the eye.
- Use the medicine only for mild irritations of the eyes.
- Use of the medicine is not recommended in complex eye conditions, such as glaucoma.
- Avoid contact of the medicine with the skin in cases of inflammation or injury, due to the presence of boric acid in the components of the medicine.
- Discontinue use and refer to the doctor if the signs of the illness (symptoms) do not improve within 3 days, or if the discomfort and redness intensify or persist, or in the event of eye pain, or if visual disturbances occur.
- Use of the medicine may cause temporary dilation of the pupil.
- Prolonged use and abuse of the medicine could cause the eye redness to intensify or reoccur.
- Remove contact lenses before using the medicine.
- To avoid contamination, do not allow contact between the tip of the vial and any surface.
- Discard the medicine if the solution changes color or if the solution becomes cloudy.

#### **Children and adolescents**

The medicine is intended for adults and children above 6 years of age.

In children from the age of 2 to 6 years: use under medical supervision.

Do not use in children under the age of two years.

The use in children under the age of 12 is under the supervision of an adult.

#### **Drug interactions**

**If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.**

#### **Pregnancy, breastfeeding and fertility**

There have been no adequate controlled studies on the use of tetrahydrozoline in pregnant or breastfeeding women.

It is not known whether tetrahydrozoline or its metabolites are excreted into breast milk.

The medicine should not be used during pregnancy or breastfeeding except in cases where the potential benefit to the mother outweighs the potential risk to the fetus or to the breastfed baby.

Consult a doctor before starting treatment if you are pregnant, planning to become pregnant or breastfeeding.

#### **Driving and operating machinery**

The use of eye drops could cause temporary blurring of vision.

#### **Important information about some of the ingredients of the medicine:**

The medicine contains boron. Do not give to a child under the age of two years as the medicine contains boron and may impair future fertility.

#### **3. How should you use the medicine?**

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

In adults and children over the age of 6, the generally accepted dosage is: 1-2 drops into each eye, up to 4 times a day. In children from the age of 2 to 6 years: use under medical supervision.

Do not use in children under the age of two years.

The use in children under the age of 12 is under the supervision of an adult.

#### **Method of use**

Wash your hands thoroughly. Tilt your head back or lie on the bed. Using your finger, slightly move the lower eyelid away from the eye. Drip the medicine into the gap that has been formed, and close your eyes for 1-2 minutes. Do not blink.

If you think the drop has not been absorbed, use another drop. Clean the remaining solution around the eye with a wipe.

#### **Do not exceed the recommended dose.**

#### **Attention!**

Do not swallow! This medicine is intended for external use only.

#### **If you accidentally took a higher dosage**

If you have taken an overdose or if a child has accidentally swallowed this medicine, go immediately to a hospital emergency room and take the package of the medicine with you (see also section 4 – "Side effects").

**If you forgot to take the medicine** at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.

**Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.**

**If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.**

#### **4. Side effects**

**As with any medicine, using Stilla Singles Eye Drops may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.**

The following are side effects that have been observed following the use of drops containing tetrahydrozoline for ocular use.

#### **Very rare side effects – side effects that occur in less than one out of 10,000 users:**

- Visual disorders – dilated pupils, increased tearing.
- Reactions at the medicine administration site (including a burning sensation in or around the eye, redness, irritation, edema, pain and itching).

#### **Additional side effects**

The frequency, type and severity of side effects in children are expected to be similar to those in adults.

Swallowing Stilla Singles Eye Drops could cause instability in the cardiovascular system (blood vessels and heart system), depression of the central nervous system (including sleepiness and coma) as well as respiratory depression, including cessation of breathing.

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.**

#### **Reporting side effects**

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.gov.il>

#### **5. How to store the medicine?**

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without explicit instructions from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

#### **Store at a temperature below 25°C.**

#### **Do not freeze the medicine.**

**Do not use the preparation for more than two months after opening the aluminum bag in which it is contained (even if you have not opened the vial).**

Discard the vial after use, even if some medicine remains in it, since the preparation does not contain a preservative.

Do not use this medicine if the solution changes color or becomes cloudy.

Do not dispose of medicines in water or in the trash. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help you protect the environment.

#### **6. Additional information**

##### **In addition to the active ingredient, the medicine also contains:**

Inactive ingredients:

Boric acid, glycerol, sodium borate decahydrate, polysorbate 80, water for injection.

##### **What does the medicine look like and what are the contents of the package:**

The package of Stilla Singles Eye Drops contains 10 or 20 single-use sterile vials. Each vial contains 0.3 ml of a clear solution.

Not all package sizes may be marketed.

##### **Marketing authorization holder and address:**

TEVA ISRAEL LTD

124 Dvora HaNevi'a St., Tel Aviv 6944020 Israel.

##### **Name and address of the manufacturer:**

Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Rome, Italy.

The leaflet was revised in October 2021 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health:

122 50 30243

#### **Instructions for use**

1. To detach the vial, move it from the top downwards and pull it towards you (Figure no. 1).



Figure no. 1

2. Gently tap the vial cap with your fingertip, to ensure no liquid remains near the opening (Figure no. 2).



Figure no. 2

3. Gently rotate the cap around itself until the vial opens (Figure no. 3).



Figure no. 3

4. Drip the medicine into the eye by continuously pressing on the bottom of the vial (Figure no. 4).



Figure no. 4

Since **Stilla Singles** drops do not contain a preservative, discard the vial after use even if you have not used the entire contents.

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