

1.3.1 Package Leaflet

Golden Eye 0.1% w/v Eye Drops Solution
Propamidine Isetionate

Patient Information Leaflet

Read all of the leaflet carefully because it contains important information for you. This medicine is available without a prescription. However, you still need to use Golden Eye 0.1% w/v Eye Drops Solution carefully to get the best results from it. Keep this leaflet. You may need to read it again. Ask your pharmacist if you need more information or advice. You must contact a doctor if your symptoms worsen or do not improve after two days. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Golden Eye 0.1% w/v Eye Drops Solution is and what it is used for
2. Before you use Golden Eye 0.1% w/v Eye Drops Solution
3. How to use Golden Eye 0.1% w/v Eye Drops Solution
4. Possible side effects
5. Storing Golden Eye 0.1% w/v Eye Drops Solution
6. Further information

1. WHAT GOLDEN EYE 0.1% w/v EYE DROPS SOLUTION IS AND WHAT IT IS USED FOR

Propamidine isetionate, the active ingredient, belongs to a group of medicines called antiseptics. Antiseptics are used to treat infections caused by bacteria.

Golden Eye 0.1% w/v Eye Drops Solution is used to treat minor eye or eyelid infections, such as conjunctivitis and blepharitis (inflammation of the eyelids).

2. BEFORE YOU USE GOLDEN EYE 0.1% w/v EYE DROPS SOLUTION

Do not use Golden Eye 0.1% w/v Eye Drops Solution and talk to your doctor or pharmacist if:

- You are allergic to propamidine isetionate or anything else contained in the eye drops (see section 6 for a full list of ingredients).
- You are pregnant or trying to become pregnant.
- You are breast feeding.
- You wear contact lenses.

Warnings and precautions

Do not use Golden Eye 0.1% w/v Eye Drops Solution and talk to your doctor or pharmacist straight away if any of the following apply to you:

- Your eye is painful (rather than just feeling sore or gritty) or you have pain or swelling around the eye or face.
- Your sight is affected by loss of vision, reduced or blurred vision or you see halos around lights.
- It is too painful to open your eyes properly.
- You have “dry eye syndrome”
- Your pupil (the black circle in the centre of your eye) looks different. It may be torn, not round, very big or does not change size in the light.
- Your eye looks cloudy.
- You have injured your eye.
- You are already using other eye drops or eye ointment.
- You think there may be something in your eye or you have splashed something in your eye.
- You have had eye surgery or laser treatment in the last 6 months.

CTD

Module 1

Version 1.2 / 2019

If you wear contact lenses and have been advised to use Golden Eye 0.1% w/v Eye Drops Solution by a doctor, pharmacist or contact lens practitioner:

- Do not wear contact lenses while using the drops.
- You should wait 24 hours after finishing using the drops before starting to use contact lenses again. This is important if you wear soft contact lenses as benzalkonium chloride, an ingredient in the drops, is known to discolour soft contact lenses.

Other medicines: Tell your doctor or pharmacist if you are taking any other medicines, including those bought without a prescription but especially other eye drops or eye ointment.

Pregnancy and breast-feeding: Do not take this medicine if you are pregnant, trying to become pregnant or breast-feeding. If you become pregnant while using the drops, stop using them and see your doctor.

Important information about some of the ingredients of this medicine: Golden Eye 0.1% w/v Eye Drops Solution contains benzalkonium chloride which may cause eye irritation.

Driving and using machinery. Golden Eye 0.1% w/v Eye Drops Solution can sometimes cause blurred vision for a short while after administration. You must not drive or operate machinery until you can see clearly again.

3. HOW TO USE GOLDEN EYE 0.1% w/v EYE DROPS SOLUTION

Always follow your pharmacist's instructions.

- Wash your hands before and after using the drops.
- Take off the bottle cap.
- Tilt head gently backwards.
- Without touching the eye with the bottle dropper, apply one or two drops to each affected eye.
- Do this up to 4 times each day. This means that you should use it about every 3 to 4 hours through the day.

If your condition does not improve after two days, stop using the drops and consult your doctor or pharmacist.

If you miss a dose, use the drops as directed above and then continue your normal course of treatment.

If the contents of this tube are swallowed, contact your doctor straight away or go to your nearest hospital casualty department. Take the container with you so that the medicine can be identified.

4. POSSIBLE SIDE EFFECTS

Most people use Golden Eye 0.1% w/v Eye Drops Solution without any problems, but like all medicines, it can have side effects. Side effects that may occur include mild hypersensitivity reactions which include stinging, burning, irritation, itching, inflammation of the skin, skin rash. If this happens to you, discontinue use and see a doctor as soon as possible. If your vision is disturbed or symptoms become worse, or you have any other unusual symptoms or concerns with your medicine, discontinue use and consult your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2. Tel: +353 1 676 4971, Fax: +353 1 676 2517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

CTD

Module 1

Version 1.2 / 2019

5. STORING GOLDEN EYE DROPS SOLUTION

- Keep all medicines out of the sight and reach of children.
- Do not store above 25°C.
- Discard within four weeks of first opening.
- Do not use it after the expiry date shown on the bottle and carton after EXP. The expiry date refers to the last day of the month.
- Always replace the top firmly on the bottle after using.
- Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Golden Eye 0.1% w/v Eye Drops Solution contains

The active ingredient is Propamidine isetionate 0.1% w/v.

The other ingredients are sodium chloride, benzalkonium chloride solution, purified water, sodium hydroxide and hydrochloric acid for pH adjustment.

What Golden Eye 0.1% w/v Eye Drops Solution looks like and contents of the pack

Golden Eye 0.1% w/v Eye Drops Solution is a clear, colourless solution available in a 10ml bottle.

Marketing Authorisation Holder: Cambridge Healthcare Ireland Limited, 20 Holles Street, Dublin 2, Ireland.

Manufacturer: Excelvision, 27 Rue de la Lombardière, 07100 Annonay, France.

This leaflet was last revised in