

GENTEAL[®] and GENTEAL[®] Gel **hypromellose and hypromellose/carbomer 980**

NAME OF THE DRUG

Eye drops

GenTeal drops, 0.3%, eye drops, solution.

Eye gel

GenTeal Gel, 0.3%, eye gel.

DESCRIPTION

Eye drops

1 g of GenTeal drops contains 3 mg hypromellose.

Excipients: Sodium perborate, sodium chloride, boric acid, potassium chloride, diethylenetriamine pentamethylene phosphonic acid, hydrochloric acid, water for injections.

Eye gel

1 g of GenTeal Gel contains 3 mg hypromellose and 2 mg carbomer 980.

Excipients: Sodium perborate, sorbitol, sodium hydroxide, diethylenetriamine pentamethylene phosphonic acid, water for injections.

PHARMACOLOGY

Pharmacodynamics

Eye drops

GenTeal lubricant eye drops are suitable for use with all types of contact lenses to increase comfort of the lens during wear or to aid in the insertion of the contact lens. The product has a buffered pH close to that of tears and contains a unique disappearing preservative, sodium perborate. Sodium perborate degrades in water to yield trace amounts of hydrogen peroxide (50-500 ppm), providing an antimicrobial action. Instilled in the eye, hydrogen peroxide is rapidly degraded by catalases to yield water and oxygen. The antimicrobial buffer system results in a solution which is free of the usual preservatives which may cause hypersensitivity or allergic reactions and yet prevents the opened bottle from becoming contaminated.

Eye gel

GenTeal Gel is a long acting eye gel for lubricating the surface of the eye for all patients with ocular discomfort. The slight hypotonicity of the gel is rapidly "neutralised" by the slightly hypertonic tear fluid caused by dry eyes. GenTeal Gel contains the same unique preservative system as GenTeal eye drops.

Pharmacokinetics

No studies were performed.

INDICATIONS

Eye drops, solution

Lubricant eye drops for wetting the surface of the eye and for wearers of all types of contact lenses.

Eye gel

GenTeal Gel soothes the sensation of dryness induced for example, by contact lenses, smoke, wind, extended computer screen use or other irritations by wetting and lubricating the surface of the eye.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

PRECAUTIONS

If eye pain, changes in vision, continued redness or irritation of the eye are noticed, GenTeal must be discontinued and a doctor should be consulted.

If GenTeal Gel changes colour or becomes cloudy, the product should not be used.

Eye drops/gels are not for injection. They should never be injected subconjunctivally, nor should they be directly introduced into the anterior chamber of the eye.

GenTeal Gel is not intended to be used during surgery.

Use in Pregnancy and Lactation

There is no experience regarding the safety of GenTeal in human pregnancy or lactation.

Interactions with Other Drugs

Eye drops

The compatibility of GenTeal eye drops has been demonstrated with lotrafilcon, tefilcon and vifilcon soft contact lenses. Optical, physical and surface properties were unchanged after soaking in GenTeal for up to 7 days.

Eye gel

GenTeal Gel can be used in combination with contact lenses. No compatibility study with lens material is available, however the results obtained with GenTeal eye drops can also be applied for GenTeal Gel.

Effects on ability to drive and use machines

Any patient who experiences blurred vision should not drive or operate machines.

ADVERSE REACTIONS

Eye drops and eye gel

GenTeal is very well tolerated by users. However, some cases of burning, stinging, allergic reactions or red eyes after instillation have been reported. Transient blurring of vision after administration has also been reported.

DOSAGE AND ADMINISTRATION

Eye drops

Adults: Instill 1 or 2 drops in each eye(s) and blink several times or apply a few drops to each lens before insertion.

Eye gel

Adults: Instil 1 or 2 drops in the conjunctival sac of the affected eye(s), as needed. The frequency of administration depends on the severity of the condition. On average, one drop is administered 1-3 times daily. If needed, GenTeal Gel may be administered more frequently. The tube must be held vertically above the eye.

Eye drops and Eye gel

Elderly: There is no indication that dosage needs to be modified for the elderly.

Paediatric use: Studies in the paediatric population have not been performed.

The dispenser remains sterile until the original closure is broken. Patients must be instructed to avoid allowing the tip of the dispensing container to contact the eyes, surrounding structures or anything else as this may contaminate the solution/gel.

If more than one medication needs to be instilled in the eye, an interval of at least 5 minutes between application of the different products must be allowed. GenTeal should be applied last.

Instructions for Use and Handling

Check bottle seal is intact before first use. If already broken do not use. Remove tamper evident ring before use.

Incompatibilities

No information available.

OVERDOSAGE

No case of overdose has been reported. As GenTeal contains no pharmacologically active ingredients, no adverse effects are likely to occur in case of overdose.

PRESENTATION**Eye drops**

Eye drops, solution. Pack size: 15mL bottle.

Eye gel

Eye gel. Pack size: 10g tube.

Storage:**Eye drops**

Store below 25°C. Close bottle after use. Discard remaining contents four weeks after opening.

Eye Gel

Store below 25°C. Close tube after use. Discard remaining contents four weeks after opening.

Poison schedule: Unscheduled.

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