

GenTeal™ Gel

Carbomer (INN) 0.22% and Hypromellose (INN) 0.3%

Pharmaceutical Form

Sterile eye gel

Composition

1 g of gel contains:

Carbomer 980 2.2 mg, Hypromellose 3 mg

Preservative: Sodium perborate tetrahydrate 0.28 mg (unique disappearing preservative)

Excip. q.s.

Pharmacodynamic Properties

GenTeal™ Gel is a long-acting eye gel to wet and lubricate the surface of the eye for all patients with ocular discomfort caused by dry eye conditions. This product contains a unique disappearing preservative, which is sodium perborate. Sodium perborate degrades with water, one of the ingredients of the GenTeal™ Gel formulation, to yield trace amounts of hydrogen peroxide, which provides an anti-microbial action. The unique anti-microbial buffer system prevents the opened bottle from becoming contaminated while avoiding preservative-related hypersensitivity reactions. Once instilled in the eye, hydrogen peroxide is rapidly degraded by enzymes present in ocular tissues to yield water and oxygen.

Pharmacokinetic Properties

No studies have been performed.

Intended use

Substitute tear fluid for the alleviation of dry eye conditions, as well as for the management of an unstable tear film.

Directions for use

Adults and elderly: Wash your hands. Place one drop in each eye (avoid touching eye with container tip) and blink several times.

GenTeal™ Gel may be used by contact lenses wearers (soft or hard), but lenses are recommended to be removed prior to instillation.

Contraindications

Do not use if you are sensitive to any of the ingredients.

Precautions

Consult your eye care professional before changing medication and before using any eye medication with contact lenses. Never touch the dropper tip of the tube to any surface including the eye, since this may contaminate the gel.

Children: Studies in children have not been performed.

Warnings

Do not use if tamper-evident seal on the tube is damaged. If you experience persistent discomfort or irritations stop using the product and consult your eye care professional. GenTeal™ Gel should not be used during surgery.

Effects on ability to drive or use machines

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

Adverse Reactions

GenTeal™ Gel is very well tolerated by users but there have been some reports of burning and stinging, allergic reactions and red eyes after instillation. If you notice any of these, discontinue and consult your eye care professional.

Interactions

No interactions studies have been carried out.

Incompatibilities

None Known.

Overdosage

No case of overdosage has been reported.

Shelf-life and precautions for storage

Do not use for longer than 1 month after opening. The unopened tube can be stored until the expiry date stated on the carton by "EXP". Close tube immediately after use.

Storage condition: See folding box

Keep out of the reach of children.

Pack sizes: Country specific pack sizes

Date of last revision of the leaflet

November 2002

Manufacturer: See folding box

® = registered trademark

Novartis Pharma AG, Basle, Switzerland

This is a medicament

- A medicament is a product that affect your health, and failure to follow the instructions may be dangerous for you.
- Follow your doctor's advice carefully, the method of use, and the instructions of the pharmacist who sold you the medicine.
- Your doctor and pharmacist are expert in the use of medicines, and their benefits and risks.
- Do not stop your course of treatment early unless advised to do so by your doctor or pharmacist.
- Do not repeat your prescription without consulting your doctor.

KEEP MEDICINES OUT OF REACH OF CHILDREN

Council of Arab Health Ministers
Union of Arab Pharmacists