

Drug Regulatory Affairs

## **Medical Device GenTeal<sup>®</sup> Drops**

(hypromellose)

**0.3% Eye Drops**

### International Medical Device Package Leaflet

#### **NOTICE**

The International Medical Device Package Leaflet (IMDPL) is the [Novartis Core Data Sheet for devices](#). It displays the company's current position on important characteristics of the product, including the safety information according to the European Medical Device Directive 93/42/EEC and the European standard for devices EN ISO 980:2003. Any national labelling for this product as a device is based on the IMDPL. However, because regulatory requirements and medical practices vary between countries, the national labelling may differ in several respects, including but not limited to the characterisation of risks and benefits.

Authors: J. M. Drexler, A. Padua

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## 1 Name of the Medical Device

GenTeal<sup>®</sup> Lubricant Eye Drops.



This leaflet contains important product use and safety information. Please read carefully and retain for future reference. Incorrect use can cause serious problems with the eyes.

## 2 Intended Use

GenTeal drops is a lubricant and wetting ophthalmic solution for people who experience sensation of dryness, fatigue or discomfort of the eyes due to environmental irritants or ocular surgery.

GenTeal drops can be used with all types of contact lenses.

## 3 Description

GenTeal drops is a sterile, slightly hypotonic, aqueous eye drop formulation containing hypromellose 0.3%.

GenTeal drops contain the GenAqua<sup>™</sup> preservative system [sodium perborate and phosphonic acid (Dequest 2060S)], which produces low levels of hydrogen peroxide as an effective germicidal agent. Upon contact with the eye surface, hydrogen peroxide is degraded into water and oxygen within 1 minute.



Processed by aseptic techniques.

## 4 Directions for Use

Wash your hands before use.

Place one or two drops in the conjunctival sac of each eye (avoid touching eye with dropper tip), and blink several times.


## 5 Contraindications (reasons not to use)

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

## 6 Precautions


Check if the bottle seal is intact before first use. If already broken or damaged do not use the product.

Once the bottle has been opened, discard any remaining product after 1 month.

Do not use the product after the expiry date  .

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.


Close the bottle after use.

Store between 8°C and 25°C  .

Never touch the dropper tip of the bottle to any surface including the eye, since this may contaminate the product.

Do not share bottles to prevent cross-contamination.

## 7 Warnings

Keep out of the reach and sight of children  .

If you experience persistent discomfort or irritation stop using the product and consult your eye care professional.

## 8 Adverse Reactions

GenTeal drops are very well tolerated. Transient blurring of vision after administration has been reported.

There have been rare reports of burning or stinging, allergic reaction, and red eyes after instillation. If you notice any of these, discontinue use and consult your eye care professional

## 9 Package Quantities

5 mL, 10 mL, 15 mL.

Dispose with the normal waste according to national laws.



CE 0123

Novartis Farma S.p.A., Largo Boccioni 1, 21040 Origgio (VA), Italy.

Information might differ in some countries.

## **10 Shelf Life**

Unopened: 24 months at 8°C to 25°C.

In use: 1 month at 8°C to 25°C.

Information might differ in some countries.

## **11 List of Excipients**

Sodium perborate tetrahydrate

Sodium chloride

Boric acid

Potassium chloride

Phosphonic acid (Dequest 2060S)

Hydrochloric acid

Water for injections

Information might differ in some countries.

## **Date of Preparation**

May 2007