Summary of product characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Eyecon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: sodium hyaluronate (biotechnologically produced with the help of a natural strain of Streptococcus)

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Eye drop, solution in unit-dose containers

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of dry eye syndrome

4.2 Posology and method of administration

Posology

Unless otherwise directed by the doctor, place 4 times a day, 1 drop in the conjunctival sac. The maximum dosage is up to 8 times daily 1 drop. However, various studies showed that more than 4 times daily applications do not lead to further improvement.

Eyecon should not be used if there is an increased risk of infection of the inner and outer eye (e.g. after eye operations or in patients susceptible to infections).

Eyecon is not recommended for use in children under 18 years of age due to lack of clinical experience.

Method of administration

Ocular use.

If different medication is additionally applied to the eye, then there should be an interval of at least 5 minutes between applications. Always administer Eyecon last. Clinical experience is only available with patients over 18 years of age.

4.3 Contraindications

Hypersensitivity to the active ingredient or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

No studies regarding the influence of Eyecon on intraocular pressure or its impact on measurement results are available.

The contact lenses do not have to be removed during the application if the ophthalmologist approves of contact lens wear for the underlying primary disease.

4.5 Interaction with other medicinal products and other forms of interaction

None known so far.

4.6 Fertility, pregnancy and lactation

No risks were demonstrated by reproduction studies, although controlled studies on pregnant women are not available.

4.7 Effects on ability to drive and use machines

Vision may be blurred briefly after application until the eye drops are distributed evenly. The patient should wait until these symptoms have cleared before driving or using machinery.

4.8 Undesirable effects

Side effects are assessed on the basis of the following frequency ratings:

Very common:	More than 1 in 10 treated persons
Common:	Less than 1 in 10, but more than 1 in 100 treated persons
Uncommon:	Less than 1 in 100, but more than 1 in 1,000 treated persons
Rare:	Less than 1 in 1,000, but more than 1 in 10,000 treated persons
Very rare:	Less than 1 in 10,000 treated persons, or not known
Unknown:	Not applicable

Occasionally, there may be a temporary burning sensation immediately after application.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il/

4.9 Overdose

Overdosage has not been observed so far.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other ophthalmics, artificial tears and other products.

ATC-Code: S01XA20

Hyaluronic acid is a naturally mucopolysaccharide. In humans, it is found mainly in skin, connective tissue, bones and in the vitreous of the eye.

Eyecon contains hyaluronate in the form of its sodium salt.

Mechanism of action

It is biotechnologically produced with the help of a natural strain of Streptococcus.

Sodium hyaluronate shows rheological non-Newtonian behaviour with relatively high viscosity in the state of rest, which reduces flow through the tear canal and prolongs the residence time of Eyecon on the eye.

This rheological property is supported by the carbomer. In contrast, the shear forces during blinking movements decrease the viscosity of Eyecon and allow the eyelids to glidewell on the cornea.

Glycerol is hygroscopic and promotes the retention of water on the cornea and conjunctiva.

5.2 Pharmacokinetic properties

Eyecon has a purely physical effect on the eye and is not absorbed.

5.3 Preclinical safety data

An acute toxicity study was conducted by the Mitsubishi Kasei Institute in conjunction with the Japanese Ministry of Health. After an oral administration of 1500 mg/kg body weight, the animals (10 mice) were observed for 14 days. No pathological changes were observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection, glycerol, carbomer 981

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

Use within 12 hours after opening of the unit dose container and within 4 weeks after opening of the sachet, Store below 25°C.

6.4 Special precautions for storage

Store below 25°C, keep containers in the inner sachets and outer package in order to protect from light.

6.5 Nature and contents of container

Packs with
20 unit dose containers
30 unit dose containers

with 0.65 ml each.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Manufacturer

Pharma Stulln GmbH
Werksstrasse 3
92551 Stulln, Germany

8. Registration Holder:

Gem Pharma Ltd.
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9. Registration Number:
116-76-29346

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