SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Artelac UNO 3.2 mg/mL Eye drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 mL of solution contains 3.2 mg of hypromellose.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye Drops, Solution
Artelac UNO is a colourless, sterile, clear solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Artelac UNO is indicated in adults and children aged more than 12 months of age for the symptomatic treatment of desiccation phenomena of the cornea and conjunctiva ("dry eye syndrome") which are caused by disturbed lacrimal secretion and functional disorders due to local or systemic diseases, or caused by deficient or incomplete eyelid closure.
Particularly suitable for patients who do not tolerate preserved formulations of artificial tears, because Artelac UNO does not contain a preservative.

4.2 Posology and method of administration

Posology
Therapy of the dry eye syndrome requires an individual dosage regimen.
The recommended dose is 1 drop into the conjunctival sac 3 to 5 times per day or as required to provide sufficient lubrication.

Generally, an ophthalmologist should be consulted when using Artelac UNO for the treatment of "dry eye syndrome", which normally turns out to be long-term or permanent therapy.

Paediatric population
Therapy of dry eye syndrome requires an individual dosage regimen.
The safety and efficacy of Artelac UNO in children aged below 12 months have not yet been established due to a not relevant use in the indication of dry eye for this range of age.

Method of administration
Ocular administration.
For instruction regarding medicinal product using and handling see section 6.6

4.3 Contraindications

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

4.4 Special warnings and precautions for use

For ophthalmic use only.

If irritation, pain, redness and changes in vision occur or worsen, treatment should be discontinued and a new assessment considered.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to hypromellose is negligible. Artelac UNO can be used during pregnancy.

Breastfeeding
Hypromellose and its metabolites are not excreted in human milk. Artelac UNO can be used during breast-feeding.

Fertility
There are no published reports of any effects of hypromellose on fertility.

Women of childbearing potential
There are no published reports of any effects of ocular hypromellose in women of childbearing potential not using contraception.

4.7 Effects on ability to drive and use machines

Artelac UNO has minor influence on the ability to drive and use machines due to transient blurring of vision after instillation. If blurred vision occurs, wait until vision has cleared before driving or operating machinery.

4.8 Undesirable effects

Adverse events are categorised by frequency as follows:

- Very common (≥1/10)
- Common (≥1/100 to <1/10)
- Uncommon (≥1/1,000 to <1/100)
- Rare (≥1/10,000 to <1/1,000)
- Very rare (<1/10,000)
- not known (cannot be estimated from the available data)

Immune System Disorders:
Very rare: Hypersensitivity (skin rash, pruritus)

Eye disorders:
Very rare:

- Hypersensitivity and intolerance reactions e.g. eye burning, pain, increased lacrimation, sensation of foreign body, conjunctival hyperaemia, eye lid swelling, pruritus.
- Eye irritation,
- Stickiness of eyelids
- Blurred vision,
- Decreased sense of smell
- Sensitivity to dazzling light.

Cases of corneal calcification have been reported very rarely in association with the use of phosphate containing eye drops in some patients with significantly damaged corneas.

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. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V*.

4.9 Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Artificial tears and other indifferent preparations, ATC code: S01XA20.
Hypromellose is a partially methylated and hydroxypropylated inert cellulose.

Mechanism of action
In the healthy eye, the corneal surface is moistened mainly by the mucin that is produced in the conjunctiva. Mucin is adsorbed on the corneal surface and forms a hydrophilic surface. In the "dry eye", and particularly in case of mucin deficiency, the administration of an artificial tear fluid is indicated. Both its surface activity and its adsorptive capacity make hypromellose particularly suitable for this use. Hypromellose has a physical-chemical action and causes, in an aqueous solution, reduced surface tension as well as increased viscosity. Hypromellose adheres well to the cornea and conjunctiva and provides adequate moistening. Symptoms of irritation caused by blinking which occur in the case of tear fluid deficiency are thus diminished and consecutive symptoms of epithelial desiccation are prevented.

Pharmacodynamic effects
Hypromellose is considered an inert substance as it has no direct pharmacological activity. The viscosity-increasing properties of hypromellose prolong the retention time and improve adhesion of the tear substitute to the cornea and conjunctiva. As a result, the tear film break-up time is prolonged and/or the tear film stability is enhanced. A stable tear film protects the cornea from desiccation phenomena and lesions of the epithelial cells

5.2 Pharmacokinetic properties

Not applicable to topical (ophthalmic) preparations. Hypromellose is not systemically absorbed.

5.3 Preclinical safety data

Non-clinical data in the literature reveal no special hazard for humans based on available studies.
Hypromellose is considered low to non-toxic and is GRAS listed. The safety of hypromellose is further supported by the widespread use in pharmaceutical and cosmetic products.

Environmental Risk Assessment (ERA)
Not applicable. Hypromellose is cellulose derived from vegetable fibre. It has no significant impact on the environment when used in the small quantities arising from use of the eye drops.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate dodecahydrate
Sodium dihydrogen phosphate dihydrate
Sorbitol E420
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C.
Do not store already opened single-dose units. Discard any unused contents in the single-dose unit after application.

6.5 Nature and contents of container

The container is a transparent low density polyethylene (LDPE) single-dose unit bottelpack-system. Each unit contains approximately 0.6 mL of solution. The units are produced by strip of 10 and packed into a suitable carton.

Artelac UNO is available in the following pack sizes:
10 x 0.6 mL single-dose containers
30 x 0.6 mL single-dose containers
60 x 0.6 mL single-dose containers
120 x 0.6 mL single-dose containers

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

The viscosity of the solution ranges from 7 to 11 mPa·s.
Concomitant ocular medication should be administered 15 minutes prior to the instillation of Artelac UNO.
To avoid contamination, do not touch the tip to the eye or any surface.

For single use only and one application for both eyes, respectively. Any unused contents should be discarded after administration.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Instruction for use:
1. Wash your hands thoroughly before applying the eye drops.
2. Wipe your eyes to clear any residual wateriness or discharge.
3. Twist off the cap of the unit
4. Tilt the head back
5. Pull your lower eyelid gently down, and then carefully place one drop inside the lower eyelid, in the corner closest to the nose.
6. Release the lower eyelid, and blink a few times to make sure the eye is covered by the liquid.
7. Repeat the procedure for your other eye.
8. When you have finished, the unit must be thrown away as it is a single dose unit.

7. MARKETING AUTHORISATION HOLDER

<[To be completed nationally]>

8. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Date of first authorisation: {DD month YYYY}>
<Date of latest renewal: {DD month YYYY}>

<[To be completed nationally]>

10. DATE OF REVISION OF THE TEXT

<{MM/YYYY}>

<[To be completed nationally]>