SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

NOVAQUA 1.4% + 0.6% Single Dose Eye Drops, Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
A single dose (0.4 ml) vial contains 5.60 mg of polyvinyl alcohol and 2.40 mg of povidone.

Excipient(s) with known effect:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops.
A clear and colorless (or slightly yellow colored) particle-free solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

It is used in cases such as dry eye syndrome (keratitis sicca) or keratoconjunctivitis sicca, where the ocular surface lubrication is impaired due to inadequate or structurally defective tear volume.

4.2. Posology and method of administration

Posology/frequency and duration of administration
The medicine is applied as 1 or 2 drops onto the affected eye(s) as needed.

Method of administration
Make sure the vial is not damaged. Twist off the cap of the vial and instill a drop into the conjunctival sac of the affected eye.

The medication in single-use vials should be used immediately after opening, and any remaining contents should be discarded after administration.

Additional information on special populations
Renal/Hepatic impairment
There are no reports for this population regarding topical ophthalmic use.

Pediatric population
There is no specific dose adjustment for children.

Geriatric population
There is no specific dose adjustment for the elderly.

4.3. Contraindications

It should not be used in cases of hypersensitivity to any of the active substances or excipients.

4.4. Special warnings and precautions for use

To avoid contamination, do not let the tip of the vial touch the eye or any surface.

Any unused portion should be discarded.

If pain, redness, irritation and changes in vision in the eye occur or worsen, the drug should be discontinued and a doctor should be consulted.

Contact lenses must be removed before each instillation but they can be reinserted 15 minutes later.

In case of concomitant use with another ocular medication, it should be administered 15 minutes prior to instillation of NOVAQUA.

If the color of the medicine changes or becomes cloudy, it should not be used.

4.5. Interactions with other medicinal products and other forms of interaction

NOVAQUA can prolong the contact time of topical drugs commonly used in ophthalmology.

Additional information regarding special populations
There are no known drug interactions.

Pediatric population
There are no known drug interactions.

4.6. Pregnancy and lactation

General recommendation
Pregnancy category is C.

Women of childbearing potential/Birth Control (Contraception)
There are no data on the use of this drug in women of childbearing potential.

Pregnancy
Safety of the use of NOVAQUA during pregnancy has not been established. However, polyvinyl alcohol and povidone do not appear to be absorbed from the gastrointestinal tract and are not metabolized following injection.

NOVAQUA should not be used during pregnancy unless clearly necessary.

Lactation
Safety of the use of NOVAQUA during lactation has not been established. However, polyvinyl alcohol and povidone do not appear to be absorbed from the gastrointestinal tract and are not metabolized following injection.

Reproduction ability / Fertility
No effects on human reproduction/fertility have been reported for topical ophthalmic use.

4.7. Effects on ability to drive and use machines

NOVAQUA has minor or moderate influence on the ability to drive and use machines as it may cause transient blurring of vision. The patients should not drive or use machinery unless vision is clear.

4.8. Undesirable effects

Very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1.000 to <1/100), rare (≥1/10.000 and <1/1.000), very rare (<1/10.000), not known (cannot be estimated from the available data).

Eye disorders
Not known: Eye irritation, eye pain, ocular hyperemia, blurred vision, eye pruritus, foreign body sensation, eye discharge and hypersensitivity

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization 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.

4.9. Overdose

No overdose cases have been reported. There is no risk in case of accidental overdose.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals – Ophthalmic lubricants
ATC code: S01XA20

NOVAQUA exerts a mechanical, not a pharmacological action. Polyvinyl alcohol enhances viscosity, while povidone enhances lubrication.

5.2. Pharmacokinetic properties

General properties
Artificial tears act like natural tears only on the ocular surface and then leave the eye surface. Ocular pharmacokinetic studies are not available, as there is no penetration into ocular tissues in topical ophthalmic application and such a feature is not expected.

5.3. Preclinical safety data

The constituents of NOVAQUA have been used safely in pharmaceutical products for many years. Topical administration in animal studies showed no untoward effects.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Sodium chloride
Sodium hydroxide or hydrochloric acid (for pH adjustment)
Water for injection

6.2. Incompatibilities

Since there are no incompatibility studies, this medicinal product should not be mixed with other medicinal products.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

Store at room temperature below 25°C.

The medication in single-use vials should be used immediately after opening, and any remaining contents should be discarded after administration.

6.5. Nature and contents of container

Available in boxes of 30 vials, each containing 0.4 ml solution.

6.6. Special precautions for disposal and other handling

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

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBER

2017/285

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of first authorization : 25.04.2017
Date of last renewal :

10. DATE OF REVISION OF THE TEXT