ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CARBOSOL 0.5 % Eye drops Solution, multi-doses recipient.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium caboxymethylcellulose 0.5 %
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops solution
Clear, colourless to yellowish solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Tears substitute used in treatment of mild to moderate symptoms of dry eyes.

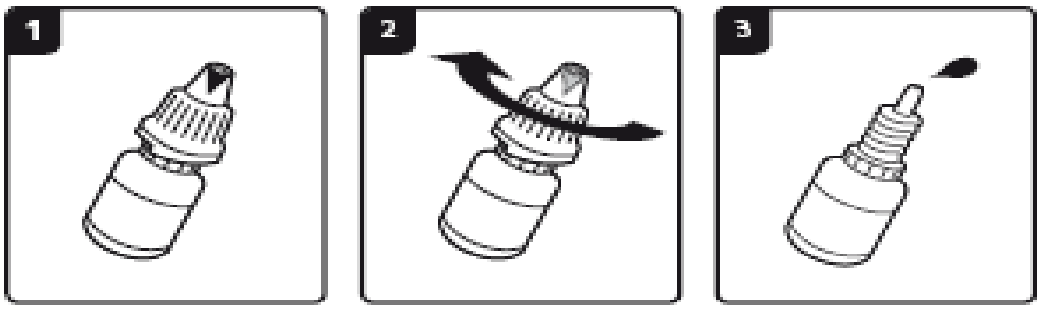
4.2 Posology and method of administration

Posology
Adults (including elderly population):
Ocular instillation
The posology is 1 drops in the affected eye(s), 2 to 4 times a day, and up to 8 times depending on the severity of the condition.

Paediatric population
Safety and efficacy of CARBOSOL in the paediatric population were not established.

Method of administration
Turn the cap to open the bottle and instil the eye drops solution.
Instil the solution in the conjunctival sac by pulling the inferior eyelid downwards while looking up.
Throw the bottle away after one month following the opening.

Bottle opening:
1. With the spike: tighten the cap on the nozzle.
2. The spike in the cap will pierce the tip of the bottle.
3. Dispense drops with gentle pressure.
4. Replace the cap after every use.



4.3 Contraindications

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

4.4 Special warnings and precautions for use

In case of apparition or aggravation of symptoms, irritation, pain, redness or changes in vision treatment should be discontinuation and a new assessment made. This eye drops solution is a multi-doses recipient presentation and contains a preservative.
To avoid any contamination, do not touch tip of the bottle, do not place directly on any surface and avoid contact with the eyes.
If you use CARBOSOL concomitantly with other ocular eyes medications, wait at least 15 minutes between the two instillations . Use the most viscous product last. CARBOSOL could delay medication absorption, it must be used last if it is the viscous one. Use the most viscous product last.
The eye drops may be used with contact lenses.
Transient blurred vision can occur when instilling the product and until it is uniformely distributed on the eye's surface.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies were conducted

4.6 Fertility, pregnancy and lactation

Pregnangy and breastfeeding
Not data are available on the use of this medicine in pregnant or breast-feeding woman. CARBOSOL will therefore be prescribed cautionsly to pregnant and breast-feeding woman.

4.7 Effects on ability to drive and use machines

CARBOSOL may cause transient blurring of vision which may impair the ability to drive or operate machines. The patient should wait until his vision has cleared before driving or use machinery.

4.8 Undesirable effects

The frequency of adverse reactions documented after using CARBOSOL are organised par organ group and listed as follows:

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

Eye disorder:
Common:
Eye irritation (including eye burning and discomfort)

Post marketing experience:
The following additional adverse drug reactions have been identified during post marketing use of the product in clinical practice after its commercialization. Because post marketing reporting of these reactions is voluntary and from a population of uncertain size, it is not always possible to reliably estimate the frequency of these reactions.

Immune system disorders:
Hypersensitivity including eye allergy including eye or eyelid swelling.

Eye disorders:
Blurred vision, tingling sensation, a feeling that something is in your eye, eye redness, eye pruritus, increased tear secretion, eye discharge, increase in tear production (also known as tearing), eye pain, crusting of the

eyelid and/or drug residue, visual disturbance.

Injury, poisons and procedural complications:
Superficial injury of eye (from the bottle tip touching the eye during administration) and/or corneal abrasion.

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 your National reporting system.

4.9 Overdose

No overdosage case was reported.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other ophtalmologicals ATC code: S01XA20.

Mechanism action
This eye drops is a corneal humidifier.
It does not have pharmacological properties but has mechanical effect (lubrification, hydration).
This eye drops is used to supplement the lack of tears by forming a transient aqueous phase
Sodium carboxymethyl cellulose in this eye drops composition is a viscosity agent derived from cellulose. Its role is to increase corneal retention time og the drops on the eyes.

5.2 Pharmacokinetic properties

There is no pharmacokinetic study on animals or humans.
Due to high molecular weight, sodium carboxymethyl cellulose is unlikely to penetrate the cornea.

5.3 Preclinical safety data

The non-clinical datas from the conventional safety pharmacology, toxicology in repeated administration, genotoxicity, cancerogenicity and reproduction pre-clinical studies did not show any particular risk to human.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride, potassium chloride, calcium chloride dihydrate, magnesium chloride, boric acid, stabilized oxychloro complex, sodium hydroxide, water for injections.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Prior to opening: 24 months.
After first opening: 1 month.

6.4 Special precautions for storage

Store below 30 °C and protected from light.

6.5 Nature and contents of container

10 mL LDPE bottle, in a cardboard box.

6.6 Special precautions for disposal

Discard any unused solution in opened container i.e. do not reuse container for subsequent doses.

7. MARKETING AUTHORISATION HOLDER

Exphar s.a.
Zoning Industriel Nivelles Sud, zone 2
Avenue Thomas Edison 105
1402 Thines - Belgium

8. NAME AND ADDRESS OF THE MANUFACTURER

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9. DATE OF REVISION OF THE TEXT

09/2021