SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Tropicil Top 5 mg/ml eye drops, solution
Tropicil Top 10 mg/ml eye drops, solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Tropicil Top 5 mg/ml: One ml of solution contains 5 mg of tropicamide.
Tropicil Top 10 mg/ml: One ml of solution contains 10 mg of tropicamide.

Excipient(s) with known effect:
Benzalkonium chloride – 0.2 mg/ml (50% solution)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, solution.
Clear, colourless and odourless solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

- Mydriasis for performing ophthalmological exams.
- Therapeutic mydriasis.

4.2. Posology and method of administration

Posology
As a cycloplegic agent, the usual dose is of two drops of the eye drops Tropicil Top 10 mg/ml, every 5 minutes, for a refraction study. Observation should be performed 20 to 40 minutes after application of the second drop.

As a mydriatic agent and for deep ocular exam, the usual dose is of one to two drops of Tropicil Top 5 mg/ml on the eye to be observed.
To keep the mydriasis for a longer period of time, it is necessary to instil one more drop every 30 minutes.

Method of administration
The eye drops should be applied in the conjunctival sac, the space between the eye and the eyelid. It is especially advisable in children to gently press the inner corner of the eyelid for 1 minute to reduce the possible systemic absorption. This should be performed immediately after the instillation of the drops.

This blocks the passage of the drops via the naso lacrimal duct to the wide absorptive area of the nasal and pharyngeal mucosa. Repeated applications of the eye drops must be avoided.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
In patients suffering from closed-angle glaucoma, with risk of camerular angle closure and of precipitating a glaucomatous crisis.

4.4. Special warnings and precautions for use

Avoid repeated instillations. The benefit-risk ratio should be taken into account when using this medicine in children with brain damage or spastic paralysis. This ratio should also be considered in cases of Down syndrome or mongolism or predisposition to closed-angle glaucoma.
Although the possibility of tropicamide systemic action through ophthalmic use is remote, the particular sensitivity of children and frail elderly to antimuscarinic drugs should always be kept in mind.
Since the use of this medication causes pupil dilation, an exaggerated sunlight sensitivity is normal. The use of sunglasses (ultraviolet blocking glass) can be helpful.

Tropicil Top contains benzalkonium chloride.
This medicine contains 0.1 mg of benzalkonium chloride in each ml of solution. Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. Remove contact lenses before using this medicine and put them back 15 minutes afterwards. Benzalkonium chloride has been reported to cause eye irritation, symptoms of dry eyes and may affect the tear film and corneal surface. Should be used with caution in dry eye patients and in patients where the cornea may be compromised. Patients should be monitored in case of prolonged use.

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

Possible existing interactions are not relevant due to Tropicil Top pharmaceutical form (eye drops, solution) and for being mainly a diagnostic auxiliary product.

4.6. Fertility, pregnancy and lactation

There are no safety studies in the animal or men. Therefore, the benefit-risk ratio should be previously considered before using this medicine in pregnant women.
The same principle is valid for women who are breast-feeding.

4.7. Effects on ability to drive and use machines

Patients should not drive or deal with machinery until full recovery from pupil dilation.

4.8. Undesirable effects

Increased intraocular pressure. Psychological and behavioural disorders and other systemic reactions have been reported in children. The following side effects may occur: transient stinging sensation, dry mouth, prolonged dilation of the pupil hindering the vision, photophobia, tachycardia, headache, parasympathetic stimulation or allergic reactions.

<u>Reporting of suspected adverse reactions</u>

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.

4.9. Overdose

Overdose manifests the exacerbation of the possible side effects which may occur with the normal use of the drug. Physostigmine is the antidote for the systemic effects of this medicinal product.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotheurapeutic group: 15.3.2 – Medicines used in eye disorders. Mydriatics and cycloplegics. Anticholinergics.
ATC code: S 01 FA 06

Tropicamide is an anticholinergic drug used to block the responses of the iris sphincter muscle and the accommodation response of the ciliary body's muscle to the acetylcholine stimulation. The 0.5% solution causes pupil dilatation (mydriasis); the 1% solution causes mydriasis as well as paralysis of the transitory accommodation (cycloplegia).

5.2. Pharmacokinetic properties

Mydriasis is achieved about 10 minutes after the instillation of one drop of the eye drops. Maximum mydriasis is achieved about 15 minutes after instillation, which is kept for about 1 hour after which it gradually decreases. The pupil resumes its initial diameter after 5 to 8 hours.
The transient accommodation paralysis is established between 20 to 40 minutes after instillation of 4 to 6 drops every 5 minutes.

5.3. Preclinical safety data

Carcinogenesis
No studies have been conducted until the present to assess the carcinogenic potential of tropicamide.

Pregnancy
No animal reproductive studies with tropicamide have been performed. Tropicamide effects in the fetus when administered to pregnant women are not known. Tropicamide should only be administered in pregnant women if the potential benefit justifies the potential risk for the fetus.

Fertility
There are insufficient data for determining whether tropicamide may affect human fertility.

Lactation
It is not known whether tropicamide is excreted in human milk. Due to the fact that many drugs are excreted in the human milk, tropicamide should be administered with precaution during lactation.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Boric acid
Benzalkonium chloride (50% solution)
Propylene glycol
Water for injections
Hydrochloric acid concentrate
Sodium chloride (for osmolality adjustment)
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

Tropicil Top 5 mg/ml eye drops, solution:
- Unopened bottle: 3 years.
- After first opening: 28 days.

Tropicil Top 10 mg/ml eye drops, solution:
- Unopened bottle: 3 years.
- After first opening: 28 days.

6.4. Special precautions for storage

Do not store above 25ºC.

6.5. Nature and contents of container

Tropicil Top eye drops, solution is supplied in LD-polyethylene bottles containing 10 ml of solution (5 mg/ml or 10 mg/ml), with HD-polyethylene cap and a LD-polyethylene dropper insert, sterilised by gamma-radiation. After filled, the bottles are packed in carton boxes properly printed, with the package leaflet.

6.6. Special precautions for disposal

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratório Edol - Produtos Farmacêuticos, S.A.
Av. 25 de Abril, 6-6A
2795-225 Linda-a-Velha
Portugal

8. MARKETING AUTHORISATION NUMBER(S)

09494/08749/VAR/2023
04448/06848/REN/2018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Sep 9, 2019

10. DATE OF REVISION OF THE TEXT

06/2021