Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Posiforlid 20 mg/g eye ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1g of eye ointment contains 20 mg Bibrocathol.

Excipient(s) with known effect: Contains wool fat.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye ointment.
Ochre, homogenous ointment.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Chronic inflammation of the lid margin (Blepharitis chronica) not requiring antibiotic treatment.

4.2 Posology and method of administration

Posology

Adults
If not otherwise prescribed, a 0.5 cm strip of eye ointment should be applied in adults 3 to 5 times daily into the conjunctival sac or on the affected position of the eye lid for a maximum of 14 days.

Adolescents and Children 6 years and older
If not otherwise prescribed, a 0.5 cm strip of eye ointment should be applied in children aged 6 to less than 18 years 3 times daily into the conjunctival sac or on the affected position of the eye lid for a maximum of 10 days.

Paediatric population
The safety and efficacy of POSIFORLID in children less than 6 years of age have not been established. No data are available.

POSIFORLID 20 mg/g may be applied until relief of the symptoms. When the complaints persist or the symptoms do not improve a physician should be consulted after 7 days.

Method of administration
For ocular use.
A contact between the tip of the tube and eye or facial skin should be avoided.

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

Woolfat may cause local skin reactions (e.g. contact dermatitis).
Contact lenses should not be worn during use of POSIFORLID 20 mg/g.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

Note: In concomitant treatment with other eye drops/eye ointments an interval of at least 1 hour should be between the applications. POSIFORLID 20 mg/g should definitely be applied at last.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of bibrocathol in pregnant women. Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). POSIFORLID 20 mg/g, eye ointment should not be used during pregnancy unless clearly necessary.

Breastfeeding
It is unknown whether bibrocathol is excreted in human milk. A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from POSIFORLID 20 mg/g, eye ointment therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility
No data on human fertility are available.

4.7 Effects on ability to drive and use machines

Due to its greasy consistency of POSIFORLID 20 mg/g eye ointment vision will be impaired after application. This affects the ability to drive and use machines. The patient should not drive and use machines until the vision is clear.

4.8 Undesirable effects

For the assessment of adverse reactions, the following frequencies of occurrence are defined:
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

Eye disorders

Rare	eye irritation including eye lid (e.g. eye itching, eye swelling, eye pain, ocular hyperaemia, burning sensation, tearing)

Immune system disorders

Rare	hypersensitivity, allergy (e. g. swelling of face, facial flushing)

Skin and subcutaneous tissue disorders

Rare	erythema, pruritus, rash

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 www.hpra.ie.

4.9 Overdose

Systemic medicinal product reactions after local application of ophthalmic ointment containing bibrocathol to the eye are not to be expected due to the extremely low penetration of the poorly soluble bibrocathol.

In the improbable event of systemic side effects following incorrect use or an accidental overdose these should be treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ophthalmologicals/ other Anti-infectives, ATC code: S 01 AX 05

Bibrocathol is a bismuth-containing substance which acts as antiseptic, adstringent and secretion inhibitng agent on mucous membranes and wounds. The mechanism of action is explained by its phenolic molecular structure consisting of tetrabromopyrocatechol and bismuth hydroxide that causes the precipitation of proteins and the shrinking of superficial layers of tissue. These activities result in the formation of a protective membrane against pathogenic invasion and non-specifically inhibit inflammation and secretion.

The efficacy and safety of the bibrocathol 2% eye ointment in the treatment of blepahritis was investigated in two double-blind, placebo-controlled, randomised studies in patients with moderately severe blepharitis / blepharoconjunctivitis which did not require antibiotic therapy. 200 patients were treated for 2 weeks three times daily, respectively 196 patients were treated three times a day for an average of 10 days. In Study 1, the primary endpoint was the mean change from baseline after two weeks, of a composite endpoint of five signs of the disease (eye lid oedema, lid erythema, debris, hyperemia and pouting of Meibomian glands) as assessed by the investigator. The maximum score was 20. The primary endpoint of Study 2 was similar, but it consisted of 4 components instead of five (minus the hyperemia), with maximal score of 16. Both studies met their primary endpoints. In Study 1, the Least Square mean change from baseline (Baseline score about 14) to Day 15 was -8.621 in the bibrocathol group and -5.996 in the placebo group (LS means difference 2.625 [95%CI: -3.360, -1.890], $p<0.0001$). In Study 2, the mean baseline values were 10.5 points, and the primary outcome difference was -2.32 points [95%-CI: -2.84; -1.80], $p<0.0001$. In both studies, the primary endpoints were supported by a secondary Patient Reported Outcome regarding ocular symptoms relief. Both studies confirmed the efficacy and safety of bibrocathol 2%-eye ointment.

5.2 Pharmacokinetic properties

Bibrocathol is almost insoluble in water and therefore does not penetrate into aqueous humour of the eye. Therefore, its ophthalmologic use is limited to the topical treatment of chronic inflammation of the lid margin (Blepharitis chronica).

There is no remarkable systemic absorption after topical application.

5.3 Preclinical safety data

Acute toxicity:
The systemic administration of single intragastric bibrocathol doses vastly exceeding the therapeutic dose temporarily accelerated respiration and decreased activity of mice, but not in rats. No mortality was observed.

Subchronic toxicity:
Multiple ophthalmologic bibrocathol doses up to 2-fold of the therapeutic dose in rats and up to 150-fold of the therapeutic dose in rabbits for 30 days did not result in appreciable adverse effects. The elevated levels of triglycerides or cholesterol determined in the blood of rabbits and rats, respectively, did not correlate with histological changes.

Genotoxicity and carcinogenicity
Bibrocathol did not show any genotoxic potential in bacteria and bone marrow cells of mice. Carcinogenicity studies were not performed.

Reproductive toxicity
In limited investigations of the reproductive toxicity in rats, ophthalmic administration of up to 2-fold of the therapeutic dose did not affect male and female fertility, embryogenesis or foetal and postnatal development.

Local tolerance in topical application:
No ocular intolerabilities of bibrocathol were observed up to maximum dosages in repeated-dose toxicity studies in rats and rabbits. Single ophthalmic administration of up to 20% bibrocathol also did not induce hypersensitivities or effects on humoral, cell-mediated or non-specific immunity of guinea pigs and mice, respectively.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White petrolatum
Liquid paraffin
Wool fat

6.2 Incompatibilities

The active substance bibrocathol is incompatible with iron (III)-salts, oxidants, strong acids and strong alkalis.

6.3 Shelf life

3 years.

After first opening: 4 weeks.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Aluminium tube with inner protective lacquer made of epoxy phenolic resin, high-density polyethylene nozzle and screw cap.
The following packsize is available:
Folding carton with one tube of 5 g.

6.6 Special precautions for disposal

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

7 MARKETING AUTHORISATION HOLDER

Taw Pharma (Ireland) Limited
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8 MARKETING AUTHORISATION NUMBER

PA23081/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th July 2025
Date of last renewal: 29th September 2026

10 DATE OF REVISION OF THE TEXT

March 2026