

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Posiforlid 20 mg/g eye ointment

Active substance: Bibrocathol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

1. What Posiforlid 20 mg/g is and what it is used for
2. What you need to know before you use Posiforlid 20 mg/g
3. How to use Posiforlid 20 mg/g
4. Possible side effects
5. How to store Posiforlid 20 mg/g
6. Contents of the pack and other information

1. What Posiforlid 20 mg/g is and what is used for

Posiforlid 20 mg/g is a disinfecting, adstringent und secretion inhibiting eye ointment.

Posiforlid 20 mg/g is used in chronic (long lasting) inflammation of the eye lid margin that are not caused by bacteria.

You must talk to a doctor if you do not feel better or if you feel worse after seven days.

2. What you need to know before you use Posiforlid 20 mg/g

Do not use Posiforlid 20 mg/g

- if you are allergic to bibrocathol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Posiforlid 20 mg/g.

Wool fat may cause local skin reactions (e.g. contact dermatitis).

Do not wear contact lenses during the use of Posiforlid 20 mg/g.

Children and adolescents

Posiforlid 20 mg/g is recommended in adolescents and children 6 years and older.

Other medicines and Posiforlid 20 mg/g

No interaction studies have been performed.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Note: If you apply other eye drops or eye ointments please leave an interval of about 1 hour between the two applications. Eye ointments should always be used at last.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

There are no data from the use of bibrocathol in pregnant women. Posiforlid 20 mg/g should not be used during pregnancy unless clearly necessary.

It is also unknown if bibrocathol is excreted in human milk. A risk to the suckling child cannot be excluded. Your doctor will decide, whether you should stop either breast-feeding or your therapy with Posiforlid 20 mg/g, eye ointment.

Driving and using machines

After application of Posiforlid 20 mg/g the eye ointment will cause a greasy film on the ocular surface that will impair vision transiently. Therefore, your ability to drive and use machines will be impaired. Do not drive and use machines until your vision is clear.

Posiforlid 20 mg/g contains wool fat

Wool fat may cause local skin reactions (e. g. contact dermatitis).

3. How to use Posiforlid 20 mg/g

Always use this medicine exactly as described in this leaflet or as your doctor has told to you. Check with your doctor if you are not sure.

The recommended dose for adults is 3 to 5 times daily a strip of about 0.5 cm into the conjunctival sac of the concerned eye.

Use in children and adolescents

The recommended dose for children ≥ 6 years is 3 times daily a strip of about 0.5 cm into the conjunctival sac of the concerned eye for a maximum of 10 days.

Instructions for use:

- Wash your hands
- Open the tube
- Do not allow the tip of the tube to touch the eye or skin.
- Remove the cap.
- Tilt your head slightly back, retract the lower eye lid slightly from the eye and apply by gently pressing on the tube a small strip of eye ointment into the conjunctival sac.
- Close the eyes slowly.
- Close the tube carefully after use.

The eye ointment can easily be applied by gently pressing on the tube without cracking or reeling up the tube.

Apply the eye ointment at regular intervals during the day.

Posiforlid 20 mg/g can be used until the symptoms are subsided.

If the complaints persist or improvement is lacking please consult a physician within seven days.

In chronic irritations of the eye an eye doctor should always be consulted. You should avoid chronic use without control.

Please consult your physician, if you have the impression that the effect of Posiforlid 20 mg/g is too strong or too weak.

If you use more Posiforlid 20 mg/g than you should

No specific measures are necessary. A short term overdose of Posiforlid 20 mg/g does not cause known side effects.

If you forget to use Posiforlid 20 mg/g

Do not use a double dose to make up for a forgotten dose, but make up for the next dose as soon as possible and afterwards continue with the same dose and the same intervals as described above or prescribed by your physician.

If you stop using Posiforlid 20 mg/g

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

For the assessment of side effects the following frequencies of occurrence are defined:

Very common:	may affect more than 1 in 10 people
Common:	may affect up to 1 in 10 people
Uncommon:	may affect up to 1 in 100 people
Rare:	may affect up to 1 in 1000 people
Very rare:	may affect up to 1 in 10,000 people
Not known:	cannot be estimated from the available data

Eye disorders

Rare	eye and eye lid irritation with following symptoms were reported: eye itching, eye swelling, eye pain, ocular hyperaemia, burning sensation, tearing
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Immune system disorders

Rare	hypersensitivity, allergy (e.g. swelling of face, facial flushing) to bibrocathol
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Skin and subcutaneous tissue disorders

Rare	erythema, pruritus, rash
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Additional side effects in children and adolescents

The same side effects that may occur in adults may also occur in children and adolescents.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

ADR Reporting:

Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Posiforlid 20 mg/g

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Shelf-life after opening: Do not use longer than 4 weeks after first opening.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Posiforlid 20 mg/g contains

The active substance is bibrocathol 20 mg/g.

The other ingredients are white petrolatum, liquid paraffin and wool fat.

What Posiforlid 20 mg/g looks like and contents of the pack

Posiforlid 20 mg/g is a yellow ointment filled into aluminium tubes with screw cap.

Each pack contains one tube with 5 g of eye ointment.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in May 2022.