

## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

### POSIFORLID 20 mg/g eye ointment

Active substance: Bibrocathol

*[For member states where the medicinal product is available on prescription only:]*

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

**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 or pharmacist has told to 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 of the 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 seven 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.

Woolfat 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

*[For member states where the medicinal product is available on prescription only:]*

Always use this medicine exactly 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.

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

The recommended dose is 3 to 5 times daily a strip of about 0.5 cm into the conjunctival sac of the concerned eye for a maximum of 14 days.

#### **Use in children and adolescents**

The recommended dose for children  $\geq 6$  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 (with prescription) / without delay (without prescription).

*[For member states where the medicinal product is available on prescription only:]*

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

In chronic irritations of the eye a 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 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**:

[see QRD Appendix V]

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

**5. How to store 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**

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

**This medicinal product is authorised in the Member States of the EEA under the following names:**

**This leaflet was last revised in MM/YYYY**