

## Package leaflet: Information for the user

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### **Liposic ® Eye Gel, 2 mg/g, Eye gel** Carbomer

**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 have 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 or pharmacist. 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.

#### **What is in this leaflet**

1. What Liposic ® Eye Gel is and what it is used for
2. What you need to know before you use Liposic ® Eye Gel
3. How to use Liposic ® Eye Gel
4. Possible side effects
5. How to store Liposic ® Eye Gel
6. Contents of the pack and other information

#### **1. What Liposic ® Eye Gel is and what it is used for**

Liposic ® Eye Gel is a whitish highly viscous gel which contains a lubricant that is used as a substitute for natural tears. Your eyes will normally produce just enough natural tears to allow them to move easily and comfortably. If your eyes do not produce enough tears they can become dry, red and painful. Liposic ® Eye Gel will help keep your eyes comfortable.

Liposic ® Eye Gel is a highly viscous gel that forms a protective layer over the eye, which keeps the surface of the eye moist.

It is easy and comfortable to use, and is particularly suitable for the symptomatic treatment of severe dry eye symptoms.

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

#### **2. What you need to know before you use Liposic ® Eye Gel**

##### **Do not use Liposic ® Eye Gel:**

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

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using Liposic ® Eye Gel.

##### **Children and adolescents aged to 18 years**

The safety and efficacy of Liposic ® Eye Gel in children and adolescents at the posology recommended in adults has been established by clinical experience, but no clinical trial data are available.

##### **Other medicines and Liposic ® Eye Gel**

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

**If Liposic ® Eye Gels used at the same time with other eye drops/eye ointments**, there should be an application time interval of approximately 15 minutes between use of such other medications and Liposic Eye Gel should always be the last medication to be applied.

### **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 taking this medicine.

Ask your doctor for advice before taking any medicine. It is possible that you will still receive it, but it is also possible that an alternative may be used.

### **Contact lenses**

In order to avoid streaks or clumps of gel collecting on the contact lenses, lenses should be taken out before application of Liposic ® Eye Gel. They can be replaced after 30 minutes.

### **Driving and using machines**

As with all eye preparations, you may have blurred vision for a little while after putting the gel in. Wait until your vision is clear before driving or using machines.

### **3. How to use Liposic ® Eye Gel**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is to place one drop of gel in the corner of the eye, nearest the nose, 3 to 5 times each day and approximately 30 minutes before going to bed.

Follow these instructions carefully.

1. Wash hands thoroughly.
2. Twist off the cap.
3. Look upwards and gently pull down the lower eyelid.
4. Hold the Liposic ® Eye Gel tube just above your eye and gently squeeze until some gel falls into the gap between your eyeball and lower eyelid.
5. Release the lower eyelid, and move your eye while open to ensure the gel covers the eye completely.
6. Repeat the process in the other eye if necessary.



### **Children and adolescents aged to 18 years**

The safety and efficacy of Liposic ® Eye Gel in children and adolescents at the posology recommended in adults has been established by clinical experience, but no clinical trial data are available.

### **If you use more Liposic ® Eye Gel than you should**

If you have instilled too much of Liposic ® Eye Gel the gel will rinse off your eyes.

### **If you forget to use Liposic ® Eye Gel**

Do not take a double dose to make up for a forgotten dose.

### **If you stop using Liposic ® Eye Gel**

**Dry eye conditions may worsen if they are treated incorrectly or inadequately.** 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.

Your eyes may sting a little when the gel is put in and your vision may become blurred. These effects will wear off within a few minutes.

A few reports of allergy (hypersensitivity) have been received following use of Liposic ® Eye Gel (may affect up to 1 in 10,000 people). This is due to one of the ingredients in the formulation.

Other side effects that have been reported rarely (may affect up to 1 in 10,000 people) include sticky eyelids, conjunctivitis (red eyes), speckling (or dots) on the cornea (the surface of the eye), swollen eyes, burning, itching, and irritation of the eye.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

#### **United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

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

## **5. How to store Liposic ® Eye Gel**

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 tube and the carton after “EXP”. The expiry date refers to the last day of that month.
- Store Liposic ® Eye Gel below 25° C (normal room temperature).
- Liposic ® Eye Gel is sterile until first opened. It is important to keep the tube as clean as possible during use.
- The tube has a flat cap, which allows it to stand in an upright position.
- Dispose of any remaining contents 28 days after first opening the tube. It may be helpful to make a written record on the tube of the date on which you opened it.
- Remember this medicine is for you. Do not give it to someone else.

## **6. Further information**

### **What Liposic ® Eye Gel contains**

The active substance is carbomer. Each tube contains 2.0 mg of carbomer in each 1 g of gel.

The other ingredients are cetrимide, sorbitol, medium-chain triglycerides, sodium hydroxide (for pH adjustment) and purified water.

Liposic ® Eye Gel is preserved with Cetrимide.

### **What Liposic ® Eye Gel looks like and contents of the pack**

Liposic ® Eye Gel is a whitish highly viscous gel.

Package size:

Tubes of 5 g gel. Packs with one or three tubes of 5 g eye gel.

Tubes of 10 g gel. Packs with one or three tubes of 10 g eye gel.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Dr. Gerhard Mann

Chem.-Pharm. Fabrik GmbH

Brunsbütteler Damm 165-173

13581 Berlin (Germany)

### **Manufacturer**

Dr. Gerhard Mann

Chem.-Pharm. Fabrik GmbH  
Brunsbütteler Damm 165-173  
13581 Berlin  
Germany  
E-Mail: kontakt@bausch.com

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

UK: Liposic Eye Gel  
Belgium: Liposic  
Greece: Liposic, Eye Gel  
Spain: Lipolac, gel oftalmico  
France: Liposic, Gel ophtalmique  
Ireland: Liposic Eye Gel  
Italy: Lipovisc  
Portugal: Liposic

**This leaflet was last revised in**

For detailed information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Bausch + Lomb UK Limited  
106-114 London Road  
Kingston upon Thames  
KT2 6TN  
[www.bausch.co.uk](http://www.bausch.co.uk)  
Tel: +44 (0) 1748 828864  
Email: bl@professionalinformation.co.uk

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**Additional INFORMATION**

Liposic ® Eye Gel is used for the symptomatic treatment of ‘dry eye’, which is a dehydration of the surface of the eye resulting from disturbances in tear secretion or tear quality. The dry eye condition can also be caused when it is not possible to close your eyelids either partly or completely.

This condition is so common that one in five patients who go to see an ophthalmologist suffers from a dry eye condition. There are many causes, such as reduced tear production in old age, air-conditioned rooms, computer work, hormonal changes during menopause, etc. Environmental and climatic effects can also play a role in the development of dry eye conditions.

**What do we understand by the term ‘dry eye’?**

During the course of the day we blink 14,000 times on an average. With each blinking motion of the eye, a very thin tear film is distributed over the surface of the eyeball, which keeps it smooth, clean and moist, and protects the eye from pollutants. When the volume or the composition of the tear film is disturbed, desiccation phenomena (drying out) of the cornea and conjunctiva occur and the patient experiences symptoms such as burning, dry eye sensation, gritty feeling, feeling of pressure, and sensitivity to light.

Liposic ® Eye Gel is a soothing gel which moistens the eye and provides tear-like lubrication to the eyes and eyelids. The carbomer in Liposic ® Eye Gel increases the thickness of the gel, which assists the gel in remaining in contact with the eye for a longer period of time. Your ophthalmologist prescribed a tear substitute for the alleviation of your eye complaints. In addition to using the preparation consistently as directed, you should follow the recommendations below:

- Let fresh air into your apartment or house several times a day
- Take care that you drink sufficiently
- Go out into the fresh air frequently
- Do not direct air vents towards your eyes

- Take breaks when working in front of a computer screen.

It is, however, also important that you consult your ophthalmologist regularly for follow-up examinations, because dry eye conditions may lead to a serious disease if they are treated incorrectly or inadequately.

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