

Package leaflet: information for the user

LIQUIVISC™ 2.5 mg/g, eye gel

Carbomer 974P

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use LIQUIVISC carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- 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.

In this leaflet:

1. What LIQUIVISC is and what it is used for
2. Before you use LIQUIVISC
3. How to use LIQUIVISC
4. Possible side effects
5. How to store LIQUIVISC
6. Further information

1. WHAT LIQUIVISC IS AND WHAT IT IS USED FOR

LIQUIVISC is a substitute for tears and contains a lubricant called Carbomer 974P.

It is an eye gel used for the relief of the **symptoms of dry eye** (such as soreness, burning, irritation or dryness) caused by your eyes not producing enough tears.

2. BEFORE YOU USE LIQUIVISC

Do NOT use LIQUIVISC:

- **if you are allergic** (hypersensitive) to Carbomer or any of the other ingredients of LIQUIVISC listed in Section 6, "What LIQUIVISC contains".

Take special care with LIQUIVISC:

- **if you wear soft contact lenses:** you must remove them before using LIQUIVISC eye gel. After using LIQUIVISC, wait at least 30 minutes before putting your lenses back in. See also in Section 2, "**LIQUIVISC contains benzalkonium chloride**".
- **if your condition worsens or has not improved** after having started treatment with LIQUIVISC: Contact your doctor.
- **DO NOT INJECT, DO NOT SWALLOW.**

Children and adolescents aged to 18 years:

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

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you have to use any other eye medicine during treatment with LIQUIVISC: first use the other eye medicine, wait 15 minutes, then use LIQUIVISC.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, **contact** your **doctor** for advice before you start using LIQUIVISC. He/she will decide if you can use LIQUIVISC.

Driving and using machines

Your sight may become blurred for a short time just after using LIQUIVISC. You should not drive or use machines until your sight is clear again.

LIQUIVISC contains benzalkonium chloride

This medicine contains 0,0015 mg benzalkonium chloride in each drop which is equivalent to 0,06 mg/g.

Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses. You should remove contact lenses before using this medicine and put them back 30 minutes afterwards.

Benzalkonium chloride may also cause eye irritation, especially if you have dry eyes or disorders of the cornea (the clear layer at the front of the eye). If you feel abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

3. HOW TO USE LIQUIVISC

If LIQUIVISC has been recommended for you then use it exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The **usual dose** of LIQUIVISC is **1 drop** in **each eye** that needs treatment, **up to 4 times a day**.

Children and adolescents aged to 18 years:

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

Instructions for use

Do not use the bottle if the **seal** around the cap is **broken** before you first open it.

Wash your hands before opening the bottle. Tilt your head back and look at the ceiling.



1. Gently pull down the lower eyelid of the eye that needs treatment until there is a small “pocket”.
2. Turn the bottle upside down. Squeeze it to release 1 drop into the “pocket”.
3. Let go of the lower lid, and blink your eyes a few times.
4. Repeat the steps 1 to 3 for the other eye, if it also needs treatment.

To help prevent infection, do not let the tip of the bottle touch your eye, the surrounding tissue or anything else. Put the screw cap back on to close the bottle, straight after you have used it. **Store** the bottle in an **upside down position** as this helps drops to form the next time you use LIQUIVISC.

Once you have **opened the bottle**, you must **not use it longer than 28 days**; please see also Section 5, “How to store LIQUIVISC”.

If you use more LIQUIVISC than you should

Using more drops of LIQUIVISC than you should will not cause you any harm.

If you forget to use LIQUIVISC

If you have missed a dose of LIQUIVISC continue with your next dose as normal.

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

4. POSSIBLE SIDE EFFECTS

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

Contact your doctor if:

- your condition worsens or has not improved after having started treatment with LIQUIVISC.

If you experience any of the following side effects just after putting in the eye gel, talk to your doctor if they worry you:

- short-lived blurring of vision
- mild short-lived stinging or feeling of burning in the eye.

The above mentioned side effects are known to occur, but the number of people likely to be affected can vary.

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

UK

The Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL – Dublin 2

Tel: +353 1 676 4971

Fax: +353 1 676 2517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

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

5. HOW TO STORE LIQUIVISC

Keep out of the reach and sight of children.

Do not use LIQUIVISC after the expiry date which is stated on the bottle label and the carton after 'EXP.'. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the bottle in the outer carton in order to protect from light.
Store the bottle in an **upside down position** as this helps drops to form the next time you use LIQUIVISC.

You must **throw away the bottle 28 days after you first opened it**, even if there are still some drops left.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What LIQUIVISC contains

- The active ingredient is Carbomer 974P 2.5 mg/g.
- The other ingredients are benzalkonium chloride, sorbitol, lysine monohydrate, sodium acetate trihydrate, polyvinyl alcohol, water for injections.

What LIQUIVISC looks like and contents of the pack

LIQUIVISC is a slightly yellow opalescent gel in a plastic bottle with a screw-cap.
Each bottle contains 10 g of eye gel.
Each pack contains 1 bottle.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Laboratoires Théa
12 rue Louis Blériot
63017 Clermont-Ferrand Cedex 2
FRANCE

Manufacturer:
URSAPHARM, Arzneimittel GmbH
Industriestrasse
66129 Saarbrücken
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:
France, Spain, Italy, Portugal, The Netherlands and Greece.....SICCAFLUID
United Kingdom and Ireland.....LIQUIVISC
Iceland and Norway.....OFTAGEL

This leaflet was last approved in 06/2020.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at THEA Pharmaceuticals Ltd, telephone number from UK 0345 521 1290, from outside UK +44 (0)345 521 1290.