

Siccafluid 2.5 mg/g

Eye gel

Carbomer 974P

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

If you have further questions, if you have any doubt, request more information to your doctor or pharmacist.

- 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 SICCAFLUID 2.5 mg/g, eye gel is and what it is used for
2. Before you use SICCAFLUID 2.5 mg/g, eye gel
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1. What SICCAFLUID 2.5 mg/g, eye gel is and what it is used for

SICCAFLUID 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 SICCAFLUID 2.5 mg/g, eye gel

Do NOT use SICCAFLUID 2.5 mg/g, eye gel:

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

Take special care with SICCAFLUID 2.5 mg/g, eye gel:

- **if you wear soft contact lenses:** you must remove them before using SICCAFLUID 2.5 mg/g, eye gel. After using SICCAFLUID, wait at least 30 minutes before putting your lenses back in. See also in Section 2, "Important information about some of the ingredients of SICCAFLUID".
- **if your condition worsens or has not improved** after having started treatment with SICCAFLUID 2.5 mg/g, eye gel: Contact your doctor.
- **DO NOT INJECT, DO NOT SWALLOW.**

Children and adolescents aged to 18 years:

The safety and efficacy of SICCAFLUID 2.5 mg/g, 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.

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 SICCAFLUID: first use the other eye medicine, wait 15 minutes, then use SICCAFLUID.

Pregnancy and breast-feeding

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

Driving and using machines

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

Important information about some of the ingredients of SICCAFLUID 2.5 mg/g, eye gel

If you wear soft contact lenses you must remove them before using SICCAFLUID eye gel. After using SICCAFLUID, you have to wait at least 30 minutes before putting your lenses back in. This is important because one of the ingredients of SICCAFLUID, called benzalkonium chloride, may cause eye irritation and can change the colour of soft contact lenses.

3. How to use SICCAFLUID 2.5 mg/g, eye gel

If SICCAFLUID 2.5 mg/g, eye gel 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 SICCAFLUID 2.5 mg/g, eye gel 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 SICCAFLUID 2.5 mg/g, 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.

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.
- 2.
- 3.



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 SICCAFLUID.

Once you have **opened the bottle**, you must **not use it longer than 28 days**; please see also Section 5, "How to store SICCAFLUID 2.5 mg/g, eye gel".

If you use more SICCAFLUID 2.5 mg/g, eye gel than you should

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

If you forget to use SICCAFLUID 2.5 mg/g, eye gel
If you have missed a dose of SICCAFLUID 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, SICCAFLUID 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 SICCAFLUID.

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 the national reporting system Agence nationale de sécurité du médicament et des produits de santé (ANSM) et réseau des Centres Régionaux de Pharmacovigilance - Site internet : www.ansm.sante.fr. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store SICCAFLUID 2.5 mg/g, eye gel

Keep out of the reach and sight of children.

Do not use SICCAFLUID 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 SICCAFLUID.

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 SICCAFLUID 2.5 mg/g, eye gel contains

The active ingredient is:

Carbomer 974P2.5 mg/g

The other ingredients are:

Benzalkonium chloride, sorbitol, lysine monohydrate, sodium acetate trihydrate, polyvinyl alcohol, water for injections.

What SICCAFLUID 2.5 mg/g, eye gel looks like and contents of the pack

SICCAFLUID 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/Operating Compagny

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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 on 03/2015.

Detailed information on this medicine is available on the web site of ANSM (France).