

Package leaflet: information for the patient

Virgan 0.15 % w/w

Eye Gel

Ganciclovir

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Virgan Eye Gel is and what it is used for

Virgan Eye Gel contains ganciclovir as the active ingredient. Ganciclovir is one of a group of active substances called anti-virals, used to treat infections caused by viruses.

This eye gel is used to treat an infection in the eye called acute herpetic keratitis in adults aged 18 years and over.

2. What you need to know before you use Virgan Eye Gel

DO NOT USE Virgan Eye Gel

If you are allergic (hypersensitive) to:

- ganciclovir or any of the other ingredients of this medicine (listed in section 6),
- acyclovir, another antiviral drug.

If you are pregnant or breast-feeding, unless your doctor tells you to.

In men and women of childbearing age unless you use a method of birth control.

Men using Virgan Eye Gel should use a local method of contraception (such as a condom) for three months after the end of treatment.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Virgan Eye Gel.

- Virgan Eye Gel contains benzalkonium chloride which 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 anormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

Contact lenses

- Benzalkonium chloride may be absorbed by soft contact lenses and may change the colour of the contact lenses.
- Remove contact lenses before using this medicine and put them back 15 minutes afterwards.

Children

Do not give this medicine to children under the age of 18 years as there is not enough information to know if it is safe in children.

Other medicines and Virgan Eye Gel

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

- If you are using any additional eye treatments:
 - ① you should wait for at least 15 minutes between using the two treatments,
 - ② Virgan Eye Gel should always be the last treatment put into the eye.
- Talk to your doctor before using this eye gel if you are taking any other medicines, especially any of the following:
 - antigout drugs such as probenecid,
 - anti-infectives such as trimethoprim/sulpha, dapsone, pentamidine, amphotericin B, imipenem/cilastatin or zidovudine,
 - anticancer therapy such as vincristine, vinblastine, adriamycin or flucytosine.

Pregnancy, breast-feeding and fertility

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 immediately, before taking this medicine.

This medicine should not be used during pregnancy and breast-feeding, unless your doctor tells you to.

Men and women of childbearing age should use a method of birth control.

Men using Virgan Eye Gel should use a local method of contraception (such as a condom) for three months after the end of treatment.

Driving and using machines

If you notice any visual disturbances (for instance, blurred vision), or if you notice any other problems with your eye sight after using this eye gel, you should not drive or operate machinery until you are satisfied that you can see clearly.

Virgan Eye Gel contains benzalkonium chloride

See section 2: What you need to know before you use Virgan Eye Gel – Warnings and precautions. This medicine contains 0.375 mg benzalkonium chloride in each tube of 5 g.

3. How to use Virgan Eye Gel

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

The recommended dose is

Adults and elderly: The usual dose is one drop of gel in each infected eye, five times per day until healed, then three times per day for 7 days.

Use in children: Virgan Eye Gel should not be used in children, unless your doctor tells you to.

The treatment should not usually exceed 21 days.

This medicine is intended to be administered into the eye (ocular use).

DO NOT INJECT. DO NOT SWALLOW.

- ① Wash your hands thoroughly before using the product.
- ② Do not touch your eye with the tip of the dropper.
- ③ While looking upwards and pulling the lower eyelid down, gently squeeze the tube to release one drop into the eye.
- ④ Press the inner corner of your eye with your fingertip for 1-2 minutes. This will prevent the drops from draining away too quickly.
- ⑤ Repeat for the other eye if necessary.
- ⑥ Close the tube after use.

Follow the instructions carefully. If there is anything you do not understand, ask your doctor or pharmacist.

Your doctor may advise you to use this medicine in a different way. Always follow your doctor's directions. Your pharmacist can also help if you are not sure.

If you forget to use Virgan Eye Gel

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

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

4. Possible side effects

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

The possible side effects are:

Eye disorders:

Very common: may affect more than 1 in 10 people

- Burning or brief tingling sensations, eye irritation, blurred vision.

Common: may affect up to 1 in 10 people

- Inflammation of the surface of the eye, (superficial punctate keratitis, such as burning or irritation, feeling like there is something in your eye, tears in the eye, sensitive to light and sometimes a small decrease in vision), redness of the conjunctiva (conjunctival hyperaemia).

Reporting of side effects

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

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Virgan 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.
- Use within 28 days of first opening.
- Do not store above 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Virgan Eye Gel contains

The active ingredient is ganciclovir 0.15 % w/w. Each gram of gel contains 1.5 milligrams ganciclovir.

The other ingredients are benzalkonium chloride (see section 2: What you need to know before you use Virgan Eye Gel), carbomer 974P, sorbitol, sodium hydroxide and purified water.

What Virgan Eye Gel looks like and contents of the pack

Your medicine is a transparent eye gel which is supplied in a tube. Each tube contains 5 g of the eye gel.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Laboratoires THEA
12, Rue Louis Blériot
63017 Clermont-Ferrand Cedex 2
FRANCE.

Manufacturer:

FARMILA - THEA FARMACEUTICI SpA
Via Enrico Fermi, 50
SETTIMO MILANESE (MI)
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The leaflet was last revised in 07/2018.

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 0345 521 1290.

