

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.
- The name of this medicine is Virgan® 0.15% w/w Eye gel but it will be referred to as Virgan Eye gel throughout the remainder of this leaflet.

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) during treatment and for three months after the end of the treatment.

Women using Virgan Eye gel should use contraceptives during treatment and for up to six months after the end of the 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 abnormal 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/ sulphamethoxazole, 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.

Women using Virgan Eye gel should use contraceptives during treatment and for up to six months after the end of the 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 0.375mg benzalkonium chloride in each tube of 5g.

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 at:

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 out of the sight and reach of children.
- Use within 28 days of first opening.
- This medicine does not require any special storage conditions.
- 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.
- If your medicine becomes discoloured or shows any signs of deterioration, return it to your pharmacist.
- 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 protect the environment.

6. Contents of the pack and other information

What Virgan Eye gel contains

Each 1g of gel contains 1.5mg of ganciclovir.

Also contains: carbomer (carbopol 974P), sorbitol, sodium hydroxide, water for injections and benzalkonium chloride.

What Virgan Eye gel looks like and contents of the pack

Virgan Eye gel is a colourless opalescent eye gel.

It is supplied in cartons containing 1 tube with a dropper nozzle and a screw cap.

Each tube contains 5g of the eye gel.

Manufactured by

FARMILA – THEA Farmaceutici S.p.A., Via Enrico Fermi,
50- 20019 Settimo Milanese (MI), Italy.

Procured from within the EU. Repackaged by the Product Licence Holder: MPT Pharma Ltd., Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall WS9 8ER.

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Leaflet dated 10th October 2024

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Ganciclovir 0.15% w/w Eye gel

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- 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.
- The name of this medicine is Ganciclovir 0.15% w/w Eye gel but it will be referred to as Ganciclovir Eye gel throughout the remainder of this leaflet.

What is in this leaflet:

1. What Ganciclovir Eye gel is and what it is used for
2. What you need to know before you use Ganciclovir Eye gel
3. How to use Ganciclovir Eye gel
4. Possible side effects
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1. What Ganciclovir Eye gel is and what it is used for

Ganciclovir 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 Ganciclovir Eye gel

DO NOT USE Ganciclovir Eye gel

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- 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 Ganciclovir Eye gel should use a local method of contraception (such as a condom) during treatment and for three months after the end of the treatment.

Women using Ganciclovir Eye gel should use contraceptives during treatment and for up to six months after the end of the treatment.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Ganciclovir Eye gel.

- Ganciclovir 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 abnormal eye sensation, stinging or pain in the eye after using this medicine, talk to your doctor.

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Other medicines and Ganciclovir Eye gel

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