

Virgan 1.5 mg/g, 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 or pharmacist.
- This medicine has been prescribed for you. 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, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What VIRGAN 1.5 mg/g, eye gel is and what it is used for
2. What you need to know before you use VIRGAN 1.5 mg/g, eye gel
3. How to use VIRGAN 1.5 mg/g, eye gel
4. Possible side effects
5. How to store VIRGAN 1.5 mg/g, eye gel
6. Contents of the pack and other information

1. WHAT VIRGAN 1.5 mg/g, eye gel IS AND WHAT IT IS USED FOR

Pharmacotherapeutic class: anti-infectives - antivirals ATC code: S01AD09.

VIRGAN is an eye gel containing an antiviral agent called ganciclovir.

It is indicated in the treatment of certain superficial and viral eye infections (cornea).

2. WHAT YOU NEED TO KNOW BEFORE YOU USE VIRGAN 1.5 mg/g, eye gel

DO NOT use VIRGAN 1.5 mg/g, eye gel

- if you are allergic to ganciclovir, aciclovir or any of the other ingredients of this medicine (listed in section 6).
- during pregnancy and breast-feeding, unless instructed otherwise by your doctor.
- in men and women of childbearing age not using a method of birth control.

Moreover, men treated by VIRGAN are advised to use a local method of contraception (such as a condom) during treatment and for three months after the end of the treatment.

Warnings and precautions

Talk to your doctor or pharmacist before using VIRGAN.

- Do not swallow.
- Avoid touching your eye or eyelids with the tip of the dropper.
- Contact lenses wearing: Avoid contact with soft contact lenses (see also **VIRGAN 1.5 mg/g, eye gel contains benzalkonium chloride**).

Children

In the absence of any specific study, use in children aged under 18 years is not recommended.

Other medicines and VIRGAN 1.5 mg/g, eye gel

If you are using any other medicine to be applied in the eye, you should:

- ① apply the other ophthalmic medicine,
- ② wait for 15 minutes,
- ③ apply VIRGAN last.

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

Pregnancy, breast-feeding and fertility

This medicine should not be used during **pregnancy** and **breast-feeding**, except where instructed otherwise by your doctor. See also section 2: Do not use VIRGAN 1.5 mg/g, eye gel.

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. Your doctor is the only one able to adjust your treatment.

Driving and using machines

You may experience temporary visual disturbances after ocular administration of the product. Wait until you have recovered normal vision before driving a vehicle or using any machine.

VIRGAN 1.5 mg/g, eye gel contains benzalkonium chloride.

This medicine contains 2.625 micrograms benzalkonium chloride in each drop of gel which is equivalent to 0.075 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 15 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 VIRGAN 1.5 mg/g, eye gel

Dosage

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is 1 drop 3 to 5 times daily.

Use in children

The use of this eye gel in children before 18 years is not recommended.

Method of administration

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

- ① Wash your hands thoroughly before using the product,
- ② Gently squeeze the tube to release a drop into the affected eye, while looking upwards and pulling the lower eyelid down,
- ③ Close the tube after use.

Duration of treatment

The treatment should not usually exceed 21 days.

If you use more VIRGAN 1.5 mg/g, eye gel than you should

Continue your treatment as instructed by your doctor. Immediately contact your doctor or pharmacist.

If you forget to use VIRGAN 1.5 mg/g, 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Eye disorders:

Very common: may affect more than 1 in 10 people

- Transient burning or stinging sensations, eye irritation, blurred vision.

Common: may affect up to 1 in 10 people

- Inflammation of the cornea (superficial punctate keratitis), redness of the conjunctiva (conjunctival hyperaemia).

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.

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

5. HOW TO STORE VIRGAN 1.5 mg/g, 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 after EXP. The expiry date refers to the last day of that month.

After opening, the tube should not be kept for more than 4 weeks.

Do not store above 30°C.

Do not throw away any medicine 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 1.5 mg/g, eye gel contains

- The active substance is:
Ganciclovir 1.5 mg
For 1 g

- The other ingredients are: carbomer (carbopol 974P), sorbitol, sodium hydroxide, benzalkonium chloride and purified water.

What VIRGAN 1.5 mg/g, eye gel looks like and contents of the pack

This medicine is supplied in a tube containing 5 g of eye gel.

Marketing Authorisation Holder

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Operating company

Thea Pharma

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