

PACKAGE LEAFLET: INFORMATION FOR THE USER

Famvir® 125, 250 and 500 mg film-coated tablets
famciclovir

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- Famvir has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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 Famvir is and what it is used for
2. Before you take Famvir
3. How to take Famvir
4. Possible side effects
5. How to store Famvir
6. Further information

1. WHAT FAMVIR IS AND WHAT IT IS USED FOR

Famvir is an antiviral medicine. It stops the infecting virus from reproducing. Since the virus reproduces very early in the infection, you will benefit most from treatment if you take Famvir as soon as the first symptoms appear.

Famvir is used to treat two types of viral infections in adults:

- Shingles (herpes zoster), which is a viral infection caused by a virus called varicella zoster (the same virus that causes chickenpox). Famvir stops the virus from spreading in the body so that healing can occur faster.
- Famvir is also used for the treatment of shingles in the area around the eye or of the eye itself (ophthalmic zoster).
- Genital herpes. Genital herpes is a viral infection caused by herpes simplex virus type 1 or 2. It is normally spread by sexual contact. It causes blisters and burning or itching around the genitals, which may be painful. Famvir is used to treat genital herpes infections in adults. People who have frequent episodes of genital herpes can also take Famvir to help to prevent the attacks.

2. BEFORE YOU TAKE FAMVIR

Do not take Famvir

- If you are allergic (hypersensitive) to famciclovir, to any of the other ingredients of Famvir listed in section 6, or to penciclovir (the active metabolite of famciclovir and an ingredient of some other medicines).

Ask your doctor for advice, if you think you may be allergic.

Take special care with Famvir

- If you have kidney problems (or have had them before). Your doctor may decide to give you a lower dose of Famvir.
- If you have problems with your body's immune system.
- If you have liver problems.

If any of these applies to you, tell your doctor before you take Famvir.

Children and adolescents (below the age of 18 years)

Famvir is not recommended for use in children and adolescents.

Prevent passing genital herpes to others

If you are taking Famvir to treat or to suppress genital herpes, or you have had genital herpes in the past, you should still practise safe sex, including the use of condoms. This is important to prevent you passing the infection on to others. You should not have sex if you have genital sores or blisters.

Taking 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.

It is especially important that you tell your doctor or pharmacist if you are taking any of the following medicines:

- Raloxifen (used to prevent and treat osteoporosis).
- Probenecid (used to treat high blood levels of uric acid associated with gout and to increase blood levels of penicillin-type antibiotics), or any other medicine that can affect your kidneys.

Taking Famvir with food and drink

You can take Famvir with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or think you may be, tell your doctor. Famvir is not to be used during pregnancy unless clearly necessary. Your doctor will discuss with you the potential risks of taking Famvir during pregnancy.

If you are breast-feeding, tell your doctor. Famvir is not to be used during breast-feeding unless clearly necessary. Your doctor will discuss with you the possible risks of taking Famvir during breast-feeding.

Driving and using machines

Famvir can cause dizziness, drowsiness or confusion. **Do not drive or use machines** if you have any of these symptoms while taking Famvir.

Important information about some of the ingredients of Famvir

If you have been told by your doctor that you have an intolerance to some sugars, e.g. lactose, contact your doctor before taking this medicine. Famvir 125 mg and 250 mg tablets contain lactose.

3. HOW TO TAKE FAMVIR

Always take Famvir exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- The daily dose and length of treatment will depend on the type of viral infection you have – see below. Your doctor will prescribe the correct dose for you.
- For the best results start the medicine as soon as possible after the first signs and symptoms appear.
- Do not have sexual contact with anyone if you have symptoms of genital herpes – even if you have started treatment with Famvir. This is because you could pass the herpes infection to your partner.
- If you have or have had kidney problems, your doctor may decide to give you a lower dose of Famvir.

Dose for shingles

If you have a normal immune system, the recommended dose is

- one tablet of 500 mg, three times a day, for seven days

If you have a reduced immune system, the recommended dose is

- one tablet of 500 mg three times a day, for ten days.

Dose for genital herpes

The dose depends on the state of your immune system, and the stage of your infection.

If you have a normal immune system, the doses are as follows:

For the *first outbreak*, the recommended dose is:

- one tablet of 250 mg three times a day, for five days.

To *treat further outbreaks*, the recommended dose is:

- one tablet of 125 mg twice a day, for five days.

To *prevent future outbreaks*, the recommended dose is:

- one tablet of 250 mg twice a day.

Your doctor will tell you how long you need to continue taking your tablets.

If you have a reduced immune system, the doses are as follows:

To *treat the current outbreak*, the recommended dose is:

- one tablet of 500 mg twice a day, for seven days.

To *prevent future outbreaks*, the dose is

- one tablet of 500 mg twice a day.

Your doctor will tell you how long you need to continue taking your tablets.

If you take more Famvir than you should

If you have taken more tablets than you have been told to take, or if someone else accidentally takes your medicine, go to your doctor or hospital for advice immediately. Show them your pack of tablets.

Taking too much Famvir may affect the kidneys. In people who already have kidney problems it may, rarely, lead to kidney failure if their dose is not correctly lowered.

If you forget to take Famvir

If you forget to take a dose of Famvir, you should take it as soon as you remember. Then take your next dose as scheduled. However, do not take two doses within a time interval of less than 1 hour, in that case you should skip the missed dose. Furthermore, 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, Famvir can cause side effects, although not everybody gets them. The side effects caused by Famvir are usually mild to moderate in intensity.

The frequency of possible side effects listed below is defined using the following convention:

- very common (affects more than 1 user in 10)
- common (affects 1 to 10 users in 100)
- uncommon (affects 1 to 10 users in 1,000)

- rare (affects 1 to 10 users in 10,000)
- very rare (affects less than 1 user in 10,000)

Serious side effects of Famvir are:

Most of these side effects are rare or uncommon (they affect between 1 to 100 in every 10,000 patients)

- **Severe blistering** of the skin or mucous membranes of the lips, eyes, mouth, nasal passages or genitals (these could be signs of a serious allergic skin reaction).
- **Unexplained bruising**, reddish or purplish patches on the skin or **nosebleeds** (these could be signs of a decrease in the number of blood platelets).
- **Swelling** below the surface of the skin (e.g. facial swelling, swelling around eye, eyelid swelling, throat swelling).
- **Yellowing** of the skin and/or eyes (signs of jaundice).

Contact a doctor or go to the emergency department at your nearest hospital straight away if you get any of these effects.

Very common side effects

- Headache

Common side effects

- Feeling sick (nausea)
- Vomiting
- Dizziness
- Rash
- Itching
- Liver function test giving abnormal results

Uncommon side effects

- Confusion
- Drowsiness (usually in older people)
- Itchy rash (urticaria)

Rare side effects

- Hallucinations (seeing or hearing things that are not really there)

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.

5. HOW TO STORE FAMVIR

- Keep out of the reach and sight of children.
- Do not use Famvir after the expiry date which is stated on the label after the expiry date. The expiry date refers to the last day of that month.
- Store Famvir tablets in their original pack. Do not store above 30°C.
- Do not use Famvir if you notice the pack is damaged or shows signs of tampering.
- 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 Famvir contains

The active substance is famciclovir.

One film-coated tablet contains 125 mg, 250 mg or 500 mg famciclovir.

The other ingredients are hydroxypropylcellulose, lactose (125 mg and 250 mg tablets only), sodium starch glycollate and magnesium stearate. The tablet coating contains hydroxypropylmethylcellulose, titanium dioxide (E171) and polyethylene glycol.

What Famvir looks like and contents of the pack

Famvir 125 mg film-coated tablets are round, white tablets marked FAMVIR or FV on one side, and 125 on the other. They come in blister packs of 10 tablets.

Famvir 250 mg film-coated tablets are round, white tablets marked FAMVIR or FV on one side, and 250 on the other. They come in blister packs of 3, 15, 21 or 56 tablets.

Famvir 500 mg film-coated tablets are oval, white tablets marked FAMVIR 500 or ORAVIR 500 or FV 500 on one side. They come in blister packs of 14, 21, 30 and 56 tablets.

Marketing Authorisation Holder and Manufacturer

The product licence holder is Novartis Pharmaceuticals UK Limited, Frimley Business Park, Frimley, Camberley, Surrey, GU16 7SR, England.

Famvir tablets are made by Novartis Farmaceutica S.A., Rhonda Santa Maria, 158 08210 Barbera Del Valles, Barcelona, Spain.

If you would like any more information, or would like this leaflet in a different format, please contact Medical Information at Novartis Pharmaceuticals UK Ltd, telephone number 01276 698370.

This medicinal product is authorised in the Member States of the EEA under the following names:

125 mg film coated tablets

Member State EU / EEA	(Invented) Name
Austria, Cyprus, Denmark, Finland, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Spain, Sweden, United Kingdom	Famvir
France	Oravir

250 mg film coated tablets

Member State EU / EEA	(Invented) Name
Austria, Cyprus, Finland, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Malta, Netherlands, Spain, Sweden, United Kingdom	Famvir

500 mg film coated tablets

Member State EU / EEA	(Invented) Name
Austria, Denmark, Finland, Greece, Iceland, Italy, Netherlands, Spain, Sweden, United Kingdom	Famvir
France	Oravir

This leaflet was last revised in February 2011.