

PACKAGE LEAFLET

Package leaflet: Information for the user

Famvir 125 mg film-coated tablets

Famvir 250 mg film-coated tablets

Famvir 500 mg film-coated tablets

Famciclovir

Read all of this leaflet carefully before you start taking 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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Do not take Famvir

- If you are allergic to famciclovir, to any of the other ingredients of this medicine (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.

Warnings and precautions

Talk to your doctor before taking 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.

Other medicines and Famvir

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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.

Famvir with food and drink

You can take Famvir with or without food.

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 for advice before taking this medicine. 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.

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.

Famvir contains lactose

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 only).

3. How to take Famvir

Always take this medicine exactly as your doctor has told you. 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 500 mg, three times a day, for seven days

If you have a reduced immune system, the recommended dose is 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 250 mg three times a day, for five days.

To *treat further outbreaks*, the recommended dose is 125 mg twice a day, for five days.

To *prevent future outbreaks*, the recommended dose is 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 500 mg twice a day, for seven days.

To *prevent future outbreaks*, the dose is 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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

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).

The frequency of the following side effects is not known (cannot be estimated from the available data):

- Purple skin patches, itching, burning (signs of inflamed blood vessels).
- Seizures or fits.
- Difficulty breathing or swallowing. Rash, itching, hives, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness. Hypotension, with or without generalised itching, skin reddening, facial/throat swelling, blue discoloration of the lips, tongue or skin (signs of severe allergic reaction).

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 (*these side effects affect more than 1 in 10 people*)

- Headache

Common side effects (*these side effects affect up to 1 in 10 people*)

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

Uncommon side effects (*these side effects affect up to 1 in 100 people*)

- Confusion
- Drowsiness (usually in the elderly)
- Itchy rash (urticaria)

Rare side effects (*these side effects affect up to 1 in 1,000 people*)

- Hallucinations (seeing or hearing things that are not really there)
- Palpitations (signs of abnormal heart beat)

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Famvir

- 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 label after the expiry date. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Store in the original package in order to protect from moisture.
- Do not use this medicine if you notice the pack is damaged or shows signs of tampering.
- Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Famvir contains

Famvir 125 mg film-coated tablets

- The active substance is famciclovir.
- The other ingredients are lactose, anhydrous, sodium starch glycolate (Type A), hydroxypropyl cellulose and magnesium stearate. The tablet coating is composed of hypromellose, titanium dioxide (E171), Macrogol 4000 and Macrogol 6000.

Famvir 250 mg film-coated tablets

- The active substance is famciclovir.
- The other ingredients are lactose, anhydrous, sodium starch glycolate (Type A), hydroxypropyl cellulose and magnesium stearate. The tablet coating is composed of hypromellose, titanium dioxide (E171), Macrogol 4000 and Macrogol 6000.

Famvir 500 mg film-coated tablets

- The active substance is famciclovir.
- The other ingredients are sodium starch glycolate, hydroxypropyl cellulose and magnesium stearate. The tablet coating is composed of hypromellose, titanium dioxide (E171), Macrogol 4000 and Macrogol 6000.

What Famvir looks like and contents of the pack

Famvir is supplied as film-coated tablets in blister packs.

Famvir 125 mg film-coated tablets

White, round, film-coated tablet, biconvex, bevelled edges, debossed with “FV” on one side and “125” on the reverse side. Blister packs of 10, 28, 30, 56 or 112 tablets. Not all pack sizes may be marketed.

Famvir 250 mg film-coated tablets

White, round, film-coated tablet, biconvex, bevelled edges, debossed with “FV” on one side and “250” on the reverse side. Blister packs of 3, 15, 21, 56 or 300 tablets. Not all pack sizes may be marketed.

Famvir 500 mg film-coated tablets

White, oval film-coated tablet, biconvex, bevelled edges, debossed with “FV 500” on one side and plain on the reverse side. Blister packs of 3, 14, 21, 30, 50 or 56 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Phoenix Labs
Suite 12, Bunkilla Plaza
Bracetown Business Park
Clonee, County Meath
Ireland

Manufacturer

Cosmo S.p.A.
Via Cristoforo Colombo, 1
20020 Lainate (Milan)
Italy

Or

LABORATORI FUNDACIÓ DAU
Pol. Ind. Consorci Zona Franca. c/C, 12-12 0804 Barcelona
Spain

[NOTE: Only the site responsible for batch release will be listed on the PIL included in the pack]

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

125mg 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

250mg 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

500mg film coated tablets

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

This leaflet was last approved in March 2020