

Package Leaflet: Information For The Patient

Famciclovir 125 mg, 250 mg, 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 Famciclovir is and what it is used for
2. What you need to know before you take Famciclovir
3. How to take Famciclovir
4. Possible side effects
5. How to store Famciclovir
6. Contents of the pack and other information

1. What Famciclovir is and what it is used for

Famciclovir contains the active substance famciclovir and 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 Famciclovir as soon as the first symptoms appear.

Famciclovir 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). Famciclovir stops the virus from spreading in the body so that healing can occur faster.
- Famciclovir 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. Famciclovir is used to treat genital herpes infections in adults. People who have frequent episodes of genital herpes can also take Famciclovir to help to prevent the attacks.

2. What you need to know before you take Famciclovir

Do not take Famciclovir

- 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 or pharmacist before taking Famciclovir:

- if you have kidney problems (or have had them before). Your doctor may decide to give you a lower dose of Famciclovir.
- 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 Famciclovir.

Children and adolescents

Famciclovir is not recommended for use in children and adolescents.

Prevent passing genital herpes to others

If you are taking Famciclovir 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 Famciclovir

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

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

- Raloxifene (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)
- any other medicine that can affect your kidneys.

Pregnancy and breast-feeding

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.

Famciclovir is not to be used during pregnancy unless clearly necessary. Your doctor will discuss with you the potential risks of taking Famciclovir during pregnancy.

Famciclovir is not to be used during breast-feeding unless clearly necessary as it is not known whether famciclovir can pass into human milk. Your doctor will discuss with you the possible risks of taking Famciclovir during breast-feeding.

If you are of child-bearing age with genital herpes, you should avoid intercourse when symptoms are present even if treatment has been started.

Driving and using machines

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

This medicine contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Famciclovir

Always take this medicine exactly as your doctor or pharmacist 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 Famciclovir. 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 Famciclovir.

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.

Method of administration

You can take Famciclovir with or without food.

If you take more Famciclovir 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 Famciclovir 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 Famciclovir

If you forget to take a dose of Famciclovir, 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. The side effects caused by Famciclovir are usually mild to moderate in intensity.

Contact a doctor or go to the emergency department at your nearest hospital straight away if you get any of the following serious side effects:

- **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)
- **Swelling** below the surface of the skin (e.g. facial swelling, swelling around eye, eyelid swelling, throat swelling)
- **Unexplained bruising**, reddish or purplish patches on the skin or nosebleeds (these could be signs of a decrease in the number of blood platelets)
- **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):

- Inflammation of blood vessels which shows as red or purple discolouration of the skin which doesn't fade
- Seizures or fits
- Difficulty breathing or swallowing. Rash, itching, hives, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness. Drop in blood pressure, with or without generalised itching, skin reddening, facial/throat swelling, blue discolouration of the lips, tongue or skin (signs of severe allergic reaction).

Other possible side effects:

Very common (may affect more than 1 in 10 people)

- Headache

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 to 100 people)

- Confusion (usually in older people)
- Drowsiness (usually in older people)
- Hives (skin rash with red, raised, itchy bumps)

Rare (may affect up to 1 in 1,000 people)

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

- Feeling the heart 'thump' in the chest (palpitations)

Reporting of side effects

If you get any side effects, talk to your doctor or 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 Famciclovir

Keep out of the sight and reach of children.

Do not store above 30°C. Store in the original package to protect from moisture.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice the pack is damaged or shows signs of tampering.

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 Famciclovir contains

The active substance is famciclovir.

125 mg tablet: Each tablet contains 125 mg of famciclovir.

250 mg tablet: Each tablet contains 250 mg of famciclovir.

500 mg tablet: Each tablet contains 500 mg of famciclovir.

The other ingredients are:

Tablet core:

Starch pregelatinised, sodium laurilsulfate, cellulose, microcrystalline, croscarmellose sodium, silica colloidal anhydrous, stearic acid.

Film-coating:

Hypromellose (E464), titanium dioxide (E171), macrogol 4000, macrogol 6000.

What Famciclovir looks like and contents of the pack

125 mg film-coated tablets: White, round, biconvex, film-coated tablets with diameter of 7.6 mm approximately.

250 mg film-coated tablets: White, round, biconvex, film-coated tablets, scored on one side with diameter of 10.6 mm approximately.

500 mg film-coated tablets: White, oval, film-coated tablets, scored on both sides with dimensions of 18.2 x 8.6 mm approximately.

250 mg and 500 mg film-coated tablets:

The tablet can be divided into equal halves. Use lower strength tablets where these are available.

Famciclovir is available in blister packs of:

125 mg: 10, 21, 120 tablets.

250 mg: 10, 15, 21, 56, 60 tablets.

500 mg: 10, 14, 21, 30, 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturers

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Specifar S.A, 1, 28 Octovriou str., Ag. Varvara, 12351 Athens, Greece.

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