

Package leaflet: Information for the user  
**Famciclovir 125 mg, 250 mg, 500 mg  
film-coated tablets**

famciclovir

The name of this medicine is Famciclovir 125 mg, 250 mg, 500 mg film-coated tablets, which will be referred to as Famciclovir throughout this leaflet.

**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 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 chicken pox). 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, which 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 (hypersensitive) to famciclovir or 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.

**Children and adolescents (below the age of 18 years)**

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 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:

- 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), or any other medicine that can affect your kidneys.

**Famciclovir with food**

You can take Famciclovir with or without food.

**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 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. Your doctor will discuss with you the possible risks of taking Famciclovir during breast-feeding.

**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.

**Famciclovir 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.

**3. How to take Famciclovir**

Always take this medicine exactly as your doctor or pharmacist has told you to. 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.

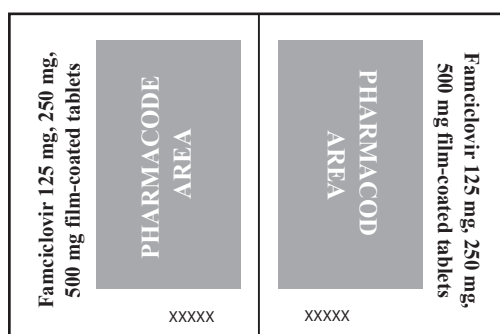
If you have a normal immune system, the doses are as follows:

- 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.

#### **Use in children and adolescents (below the age of 18 years)**

Famciclovir is not recommended for use in children and adolescents.

#### **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 stop taking Famciclovir**

It is important that you take all of the tablets prescribed by your doctor. You should not stop taking your medicine without taking to the doctor first, even if you feel well.

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.

#### **Serious side effects of Famciclovir 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.

The following side effects may also occur:

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

- Headache

**Common side effects** (may 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** (may affect up to 1 in 100 people)

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

**Rare side effects** (may 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 or pharmacist. 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](http://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 this medicine out of the sight and reach of children.
- 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.
- Store in the original package.
- 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 to protect the environment.

### 6. Contents of the pack and other information

#### **What Famciclovir contains**

- The active substance is famciclovir. Each tablet contains 125 mg, 250 mg or 500 mg famciclovir.
- The other ingredients are lactose monohydrate, croscarmellose sodium, crospovidone and magnesium stearate. The film coat contains hypromellose 15cP, titanium dioxide (E171) and macrogol.

#### **What Famciclovir looks like and contents of the pack**

Famciclovir 125 mg film-coated tablets are white to off white coloured, circular, biconvex film-coated tablets, plain on both sides. They are supplied in blister packs containing 10 tablets.

Famciclovir 250 mg film-coated tablets are white to off white coloured, circular, biconvex film-coated tablets, plain on both sides. They are supplied in blister packs containing 3, 15, 21 or 56 tablets.

Famciclovir 500 mg film-coated tablets are white to off white coloured, capsule shaped, biconvex film-coated tablets, plain on both sides. They are supplied in blister packs containing 14, 21, 30 and 56 tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

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**Product License Number: PL 20395/0256 - 0258**

**This leaflet was last revised in January/2019**