

# **Famciclovir 125mg, 250mg, 500mg, 750mg film-coated tablets**

**Read all of this leaflet carefully before you start using this medicine.**

- 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 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 famciclovir is and what it is used for
2. Before you use famciclovir
3. How to use famciclovir
4. Possible side effects
5. How to store famciclovir
6. Further information

## **1. WHAT FAMCICLOVIR IS AND WHAT IT IS USED FOR**

Famciclovir belongs to a group of medicines called antiviral agents. These are medicines used in the treatment of infections caused by viruses.

Famciclovir is used in patients with a normal immune system to treat attacks of genital herpes. Genital herpes is a viral infection which is normally spread by sexual contact. It causes blisters and burning around your genitals, which may be painful.

It is also sometimes used to prevent further episodes of genital herpes in patients with a normal immune system.

Famciclovir is used in the treatment of shingles in both patients with a normal immune system and in patients with a weakened immune system. Shingles is caused by a virus called herpes zoster or varicella zoster.

It is used in the treatment of herpes zoster infections of the eye in patients with a normal immune system.

Famciclovir is used in patients with a weakened immune system for the treatment of infections caused by herpes simplex virus, such as genital herpes or fever blisters (herpes labialis).

## **2. BEFORE YOU USE FAMCICLOVIR**

**Do not use famciclovir**

- if you are allergic (hypersensitive) to famciclovir, penciclovir or any of the other ingredients of famciclovir.

**Take special care with famciclovir**

- if you have kidney problems. You should talk with your doctor before you begin treatment with famciclovir, as it may be necessary to adjust your dosage.

As genital herpes is a sexually transmitted disease, you should avoid sexual activity if you have any symptoms of herpes, even if you have started treatment, to reduce the risk of spreading the disease to your partner. You should also take appropriate steps for protected intercourse if you are on long-term treatment with famciclovir for the same reason. Patients should therefore take appropriate steps for protected intercourse (i.e. use condoms).

Consult your doctor if one of the above-mentioned warnings applies to you, or has applied to you in the past.

**Using 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.

If you are taking other medicines at the same time as famciclovir, these medicines may interfere with each other. This might be harmful. The effects of the medicines could be increased or diminished and side effects could occur more easily.

In particular this applies to:

- probenecid, a medicine against viruses and gout
- some painkillers such as acetylsalicylic acid and ibuprofen

**Using famciclovir with food and drink**

Famciclovir can be taken with or without food. Swallow the tablets with water.

**Pregnancy and breast-feeding**

**Pregnancy**

It is not known if it is safe to use famciclovir during pregnancy. Famciclovir must not be used during pregnancy, unless it is absolutely necessary and only in accordance with your doctor's instructions.

**Breast-feeding**

There is limited experience with famciclovir in breast-feeding women. Therefore, it should not be used during breast-feeding unless you are directly instructed to do so by your doctor.

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

**Driving and using machines**

In rare instances, use of famciclovir may have side effects, such as dizziness, drowsiness and confusion. If you experience any such side effects then do not drive or operate machinery.

## **3. HOW TO USE FAMCICLOVIR**

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

Treatment with famciclovir should start as soon as possible after the symptoms of eruption/rash appear.

You should keep taking the medicine even if there is no improvement, as it may take several days for the medicine to work.

Keep taking the tablets until you have used the whole pack, unless your doctor has given you other instructions. Use lower dosage strength tablets, where these are available.

*Adults*

Recurrent genital herpes infection in patients with a normal immune system: 250mg twice daily.

In the treatment of genital herpes, you should start taking famciclovir as soon as possible after the occurrence of the first symptoms (pain, burning sensation, blisters).

First outbreak of genital herpes in patients with a normal immune system: 250mg three times daily.

In the treatment of genital herpes, you should start taking famciclovir as soon as possible after the occurrence of the first symptoms (pain, burning sensation, blisters).

Prevention of further recurrences of genital herpes in patients with a normal immune system: one 250mg tablet twice daily.

Prevention of recurring outbreak of genital herpes in HIV patients: 500mg twice daily.

Genital herpes infection in patients with a weakened immune system: 500mg twice daily.

In the treatment of genital herpes, you should start taking famciclovir as soon as possible after the occurrence of the first symptoms (pain, burning sensation, blisters).

Fever blisters in patients with a weakened immune system: 500mg twice daily.

In the treatment of a fever blister (herpes labialis), you should start taking famciclovir as soon as possible after the occurrence of the first symptoms of the infection (pain, burning sensation, blisters).

Shingles in patients with a normal immune system: 500mg three times daily.

In the treatment of shingles (herpes zoster), you should start taking famciclovir as soon as possible (within 48 hours) after the occurrence of the first symptoms of the infection (rash).

Herpes zoster infection of the eye in patients with a normal immune system: 500mg three times daily or 750mg twice daily\* for 7 days.

\* Only relevant for the 750mg strength.

Shingles in patients with a weakened immune system:  
500mg three times daily.

In the treatment of shingles (herpes zoster), you should start taking famciclovir as soon as possible (within 48 hours) after the occurrence of the first symptoms of the infection (rash).

#### *Patients with kidney problems*

Depending on how severely the function of your kidneys is affected, your doctor may reduce the dose of famciclovir you must take.

#### *Elderly patients*

Your doctor may adjust your dosage of famciclovir according to your kidney function.

#### *Children*

Famciclovir is not recommended for use in children below 18 years of age due to lack of data on safety and efficacy.

#### **Duration of treatment**

Treatment of genital herpes in patients with a normal immune system: 5 days.

Treatment of genital herpes in patients with a weakened immune system: 7 days.

Prevention of recurrence of genital herpes in patients with a normal immune system: 6-12 months. You should only take famciclovir for as long as your doctor has told you.

Shingles in patients with a normal immune system: 7 days.

Shingles in patients with a weakened immune system: 10 days.

Fever blisters in patients with a weakened immune system: 7 days.

#### **If you use more famciclovir than you should**

Contact your doctor or pharmacist if you have taken more famciclovir than stated in this leaflet, or more than the doctor has prescribed.

Rarely, acute kidney failure has occurred in patients with existing kidney disease when the dose of famciclovir was not adjusted accordingly.

#### **If you forget to use famciclovir**

If you forget to take the medicine, take it as soon as you remember, or skip the forgotten tablet if it is time for your next dose. Then continue taking the tablets as normal.

Do not take a double dose to make up for a forgotten dose. If you have forgotten several doses, you should contact your doctor.

#### **If you stop using famciclovir**

Do not stop taking famciclovir without consulting your doctor first.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

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

The following side effects may occur:

*Common side effects (occur in 1 to 10 users in 100)*

- Headache
- Nausea, diarrhoea, vomiting, abdominal pain, constipation
- Increased sweating
- Itching

*Rare side effects (occur in 1 to 10 users in 10,000)*

- Confusion (mainly in elderly patients)

*Very rare effects (occur in less than 1 user in 10,000)*

- Blood disorders (shortage of blood cells, called blood platelets that help blood to clot) accompanied by bruises and proneness to bleeding (so-called thrombocytopenia)
- Hallucinations (seeing and hearing things that are not really there)
- Dizziness, fatigue (tiredness), drowsiness (primarily in elderly patients)
- Yellowing of the skin and eyes (jaundice)
- Abnormal liver function tests

- Severe skin reactions, such as serious allergic reactions (hypersensitivity) with (high) temperature, dark red patches on the skin, joint pains and/or eye infections (so-called Stevens-Johnson syndrome), acute severe (hypersensitivity) reactions associated with fever and blisters on the skin, shedding of skin (so-called toxic epidermal necrolysis) or rash with reddish (weeping) irregular patches (so-called erythema multiforme); rash, nettle rash

*Not known (cannot be estimated from the available data)*

- Fever

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 FAMCICLOVIR**

Keep out of the reach and sight of children.

Do not store above 30°C.

Store in the original package to protect from moisture.

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

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 Famciclovir Tablets contain**

The active substance is famciclovir.

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

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

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

750mg tablet: each tablet contains 750mg 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 Tablets look like and contents of the pack**

125mg film-coated tablets:

white, round, biconvex,

film-coated tablets with diameter

of 7.6mm approximately.

250mg film-coated tablets: white, round, biconvex,

film-coated tablets, scored on one side with diameter of

10.6mm approximately.

500mg film-coated tablets: white, oval, film-coated tablets,

scored on both sides with dimensions of 18.2 x 8.6mm

approximately.

750mg film-coated tablets: white, oval, film-coated

tablets with dimensions of 20.5 x 9.8mm approximately.

250mg and 500mg film-coated tablets: The tablet can be

divided into equal halves. Use lower strength tablets

where these are available.

Famciclovir Tablets are available in blister packs of:

125mg: 10 tablets

250mg: 15, 21, 56 tablets

500mg: 14, 30, 56 tablets

750mg: 7 tablets

Not all pack sizes may be marketed.

##### **Marketing Authorisation Holder and Manufacturer**

Winthrop Pharmaceuticals, PO Box 611, Guildford, Surrey, GU1 4YS, UK

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