

Package leaflet: Information for the user

## Famvir® 500mg 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.

The name of your medicine is Famvir 500mg film-coated tablets but will be referred to as Famvir throughout this leaflet. Please note that this leaflet also contains information about the other strengths Famvir 125mg and 250mg film-coated tablets.

### 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 125mg and 250mg 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 500mg three times a day, for seven days.

If you have a reduced immune system, the recommended dose is 500mg 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 250mg three times a day, for five days.

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

To *prevent future outbreaks*, the recommended dose is 250mg 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 500mg twice a day, for seven days.

To prevent future outbreaks, the dose is 500mg 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 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 effect** (*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 effect** (*these side effects affect up to 1 in 100 people*)

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

**Rare side effect** (*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 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 Famvir

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

Do not take the tablets after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.

If the tablet becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Remember if your doctor tells you to stop taking this medicine, return any unused medicine to your pharmacist for safe disposal. Only keep this medicine if your doctor tells you to.

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. Contents of the pack and other information

##### What Famvir contains

The active ingredient in the Famvir is famciclovir. Each film-coated tablet contains 500mg famciclovir. The other ingredients are sodium starch glycolate (type A), hydroxypropylcellulose and magnesium stearate.

Tablet coating: hypromellose, titanium dioxide (E171), Macrogol 4000 and Macrogol 6000.

##### What Famvir looks like and contents of the pack

Famvir is white, oval, biconvex film-coated tablet with bevelled edges, debossed with 'FV 500' on one side and plain on the other side.

It is available in pack size of 14 tablets.

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

##### OR

Laboratori Fundacio DAU, Pol. Ind. Consorci Zona Franca. c/ C, 12-14, 08040 Barcellona, Spain.

**Procured from within the EU and repackaged by the Product Licence holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Famvir® 500mg film-coated tablets; PL 18799/4103**

Leaflet date: 17.01.2024



Famvir is the registered trademark of Sandoz AG.

Blind or partially sighted?  
Is this leaflet hard to see or read?  
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**Famciclovir 500mg film-coated tablets**

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**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 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).
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**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 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 (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:

- Raloxifen (used to prevent and treat osteoporosis).
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**Famciclovir with food and drink**

You can take Famciclovir 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. 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.

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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 (Famciclovir 125mg and 250mg tablets only).

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**Dose for shingles**

If you have a normal immune system, the recommended dose is 500mg three times a day, for seven days.

If you have a reduced immune system, the recommended dose is 500mg 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 250mg three times a day, for five days.

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

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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:

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To *prevent future outbreaks*, the dose is 500mg twice a day.

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#### **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.

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#### **4. Possible side effects**

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

##### 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).

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

- Headache

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

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- Liver function test giving abnormal results

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- Itchy rash (urticaria)

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

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#### **5. How to store Famciclovir**

Keep out of the sight and reach of children.

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

##### **What Famciclovir contains**

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The other ingredients are sodium starch glycolate (type A), hydroxypropylcellulose and magnesium stearate.

Tablet coating: hypromellose, titanium dioxide (E171), Macrogol 4000 and Macrogol 6000.

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**PL 18799/4103**

Leaflet date: 17.01.2024

**POM**

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## Is this leaflet hard to see or read?

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