

PATIENT INFORMATION LEAFLET
FAMCICLOVIR 125, 250 and 500mg FILM-COATED TABLETS
(famciclovir)



The name of this medicine is Famciclovir 125, 250 and 500 Film-coated Tablets, which will be referred to as Famciclovir Tablets throughout this leaflet

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please 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 Tablets are and what they are used for
2. Before you take Famciclovir Tablets
3. How to take Famciclovir Tablets
4. Possible side effects
5. How to store Famciclovir Tablets
6. Further information

1. WHAT FAMCICLOVIR TABLETS ARE AND WHAT THEY ARE 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).
- 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. BEFORE YOU TAKE FAMCICLOVIR TABLETS

Do not take Famciclovir Tablets:

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

Take special care with Famciclovir Tablets

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

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.

Taking 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.

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.

Taking your medicine with food and alcohol

You can take Famciclovir Tablets with or without food.

Pregnancy, breast-feeding and fertility

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

If you are pregnant or think you may be, tell your doctor. 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.

If you are breast-feeding, tell your doctor. 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

In rare cases famciclovir can cause dizziness, drowsiness or confusion. **Do not drive or use machines** if you have any of these symptoms while taking Famciclovir Tablets

Important information about some of the ingredients of Famciclovir Tablets

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 125 mg, 250 mg and 500mg tablets contain lactose.

3. HOW TO TAKE FAMCICLOVIR TABLETS

Always take famciclovir exactly as your doctor has told you. You should 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.

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FAMCICLOVIR FILM-COATED TABLETS 	FAMCICLOVIR FILM-COATED TABLETS 
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Cipla Inventory Code

PACKAGING DEVELOPMENT

Product Name : Famciclovir 125 250 500 750mg Tab. (PIL)		Item Code : XXXXX	Date : 04.04.11
Cordinator : Pawan		Artist : Atul	Software : Illustrator CS2
Fonts : Convert to curve			
Colours : BLUE WOOL TEST VALUE 5-8 (LIGHT FASTENING DATA)  Black			
Supersedes / Reference		Screen : #	Unwinding Direction :
Tuck flap: ___ mm		Side / Collar flap overlap: yes / no	
Links :			
Pharmacode : 200_std.		Design : Folded	
Material : 54 GSM JK Maplitho Paper.		Varnish :	
Actual Size : 180 x 394mm		Size after Folding : 45 x 24mm	
Print repeat length :			
Grain Direction : Perpendicular to Crease / Perpendicular to Pasting Flap / Parallel to length			
Reference / Instructions / Remark / Braille Text Embossing:			
Path : F:atul/Pawan/Neolab/Famciclovir Neolab UK/Famciclovir 125 250 500 750mg Tab. (PIL).ai			
Checked by	Artist	Cordinator	Section Head
Pharma Code / 2D Code			
Barcode Code			
Artwork			Date:

Font: Arial / Arial Bold

Body text : 9pt
 Sub Heading : 10pt
 Main Heading : 12pt

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.

If you take more Famciclovir Tablets 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 Tablets:

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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE-EFFECTS

Like all medicines, famciclovir can cause side effects, although not everybody gets them. The side effects caused by famciclovir are usually mild to moderate in intensity.

The frequency of possible side effects listed below is defined using the following convention:

- very common (affects more than 1 user in 10)
- common (affects 1 to 10 users in 100)
- uncommon (affects 1 to 10 users in 1,000)
- rare (affects 1 to 10 users in 10,000)
- very rare (affects less than 1 user in 10,000)

Serious side effects of famciclovir are:

- **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, for frequency see below).
- **Unexplained bruising**, reddish or purplish patches on the skin or **nosebleeds** (these could be signs of a decrease in the number of blood platelets, for frequency see below).

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

- Headache

Common side effects

- Feeling sick (nausea)
- Vomiting
- Dizziness
- Drowsiness
- Rash
- Pruritus
- Liver function test giving abnormal results

Uncommon side effects

- Confusion
- Severe skin reactions

Rare side effects

- Hallucinations (seeing or hearing things that are not really there)
- Yellowing of the skin and/or eyes
- Low platelet count

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 TABLETS

- Keep this medicine out of the sight and reach of children.
- Do not use Famciclovir Tablets after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
- Store your tablets in the original package.
- Do not use Famciclovir Tablets if you notice the pack is damaged or shows signs of tampering.
- 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.

They also contain: lactose monohydrate, croscarmellose sodium, crospovidone and magnesium stearate. The tablet contains Opadry White: hypromellose, titanium dioxide (E171) and macrogol.

What Famciclovir Tablets look like and contents of the pack:

Famciclovir Tablets are white to off-white coloured, circular (125mg & 250mg), capsule-shaped (500mg), biconvex film-coated tablets plain on both sides.

Famciclovir 125 mg Tablets come in packs of 10 tablets.

Famciclovir 250 mg Tablets come in packs of 15, 21 or 56 tablets

Famciclovir 500 mg Tablets come in packs of 14, 30 or 56 tablets.

Marketing Authorisation Holder and Manufacturer:

The Marketing Authorisation Holder and manufacturer responsible for batch release is Neolab Ltd, 57 High Street, Odiham, Hampshire, RG29 1LF UK.

This information is available in alternative formats upon request.

This leaflet was last approved in: MM/YYYY



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