**Famiciclovir 125mg, 250mg or 500mg Film-coated Tablets**

**Famiciclovir Tablets** are 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). Famiciclovir stops the virus from spreading in the body so that healing can occur faster.
- Herpes simplex virus type 1 or 2. It is normally spread by sexual contact. It causes blisters and burning or itching around the genital area, which usually heal. Famiciclovir 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.

**Do not take Famiciclovir Tablets:**
- If you are allergic to famciclovir or 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).
- If you have ever had pancreatitis.
- If you have liver problems.
- If you have kidney problems (or have had them before). Your doctor will discuss with you the potential risks of taking famciclovir during pregnancy or breast-feeding.
- If you are allergic to penciclovir or 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 Famiciclovir Tablets.

This is especially important if any of the following apply to you:
- If you have kidney problems (or have had them before). Your doctor will discuss with you the potential risks of taking famciclovir during pregnancy or breast-feeding.
- If you have problems with your body’s immune system.
- If you have liver problems.
- If you are allergic to penciclovir or 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).

**Children and adolescents**
Famiciclovir tablets are not recommended for use in children and adolescents.

**Prevent passing genital herpes to others**
If you are taking Famiciclovir Tablets to treat or to suppress genital herpes, or you have had genital herpes in the past, you should still practice 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 Famiciclovir Tablets**
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:
  - Raltegravir (used to prevent and treat HIV infection).
  - Raltegravir (used to treat high blood levels of uric acid associated with gout and to increase blood levels of penicillin-type antibiotics).

**Pregnancy and breast-feeding**
You can take Famiciclovir Tablets with or without food.

**Driving and using machines**
Famiciclovir Tablets can cause dizziness, drowsiness or confusion. Do not drive or use machines if you have any of these symptoms while taking famciclovir.

**Dosage and storage**
Famiciclovir Tablets are not recommended for use in children and adolescents.

**Preventing outbreaks of shingles**
If you have had shingles, tell your doctor or pharmacist before taking Famiciclovir Tablets.

**Preventing outbreaks of genital herpes**
If you have had genital herpes before, tell your doctor or pharmacist before taking Famiciclovir Tablets.

**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. See section 4.

**Contents of the pack and other information**
For the full details of the risks and benefits of this medicine, please read the Summary of Product Characteristics or the full Prescriber’s Information leaflet that comes with the medicine.

**Further information**
If you still have any questions, ask your doctor or pharmacist.

**Packaging and storage**
Famiciclovir Tablets are supplied in screw cap bottles containing white film-coated tablets. The tablets are available in 125mg, 250mg and 500mg strengths.

**For Printing Colour**
1. Item no: AAA0432
2. Print proof no: 2
3. Origination date: 16/06/15
4. Revised by: dje
5. Revision date: 29.06.15
6. Supplier: Actavis Malta Zejtun

**Technical Approval**
Date sent: N/A
- Misspellings and extra numbers are not the responsibility of the Artwork Studio.
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 episode, the recommended dose is: - one tablet of 500 mg twice 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 further outbreaks, the recommended 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 have a reduced immune system, the doses are as follows:

- Treat the current outbreak, the recommended dose is: - one tablet of 500 mg twice a day, for seven days.

To prevent further 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 many Famciclovir Tablets 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 Tablets, you should take it as soon as you remember. Then take your next dose as scheduled. Do not take a double dose to make up for a forgotten dose.

If you take more Famciclovir Tablets than you should

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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.

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

- very common: may affect more than 1 in 10 people
- common: may affect up to 1 in 10 people
- uncommon: may affect up to 1 in 100 people
- rare: may affect up to 1 in 1,000 people
- very rare: may affect up to 1 in 10,000 people

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).
- Swelling of the face, eyes, lips and/or throat which make it difficult to swallow or breathe (these could be signs of a severe allergic reaction called angioedema).
- 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
- Diarrhea
- 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.

Reporting of side effects

If you get any side effects, talk to your doctor, 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE FAMCICLOVIR TABLETS

Keep this medicine out of the sight and reach of children.

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

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

Do not use Famciclovir Tablets 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. FURTHER INFORMATION

What Famciclovir Tablets contain:

- The active substance is famciclovir. Each film-coated tablet contains 125mg, 250mg or 500mg of famciclovir.
- The other ingredients in the tablet core are microcrystalline cellulose, sodium starch glycolate (type A), hydroxypropyl cellulose and magnesium stearate. The tablet coat is Opadry II BSF18378 White which contains polyvinyl alcohol, titanium dioxide (E-171), macrogol 3350 and talc.

What Famciclovir Tablets look like and contents of the pack:

Your medicine is in the form of film-coated tablets.

The 125mg tablets are white, round, film-coated tablets with ‘FC’ over ‘125’ on one side and ‘>’ on the other. The expiry date is stated on the blister and carton after EXP. The 250mg tablets are white, round, film-coated tablets with ‘FC’ over ‘250’ on one side and ‘>’ on the other. The 500mg tablets are white, capsule-shaped, film-coated tablets with ‘FC 500’ on one side and ‘>’ on the other.

Famciclovir 125mg tablets are available in blisters containing 10, 30 or 56 film-coated tablets.

Famciclovir 250mg tablets are available in blisters containing 15, 21, 30 or 56 film-coated tablets.

Famciclovir 500mg tablets are available in blisters containing 14, 21, 30 or 56 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Actavis Group PTC etf, Reyjavikurverpi 7B-7B
220 Hallanfjarður, Iceland

Manufacturer:

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