

**FAMCICLOVIR 750MG FILM-COATED TABLETS  
PL 00289/1089**

**UKPAR**

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**FAMCICLOVIR 750MG FILM-COATED TABLETS  
PL 00289/1089**

**LAY SUMMARY**

On 11<sup>th</sup> March 2009, the MHRA granted Teva UK Limited a licence for the medicinal product Famciclovir 750mg Film-Coated Tablets (PL 00289/1089). This is a prescription-only medicine (POM) to treat infections caused by the *herpes zoster* virus, which causes shingles.

Famciclovir 750mg Film-Coated Tablets contain the active ingredient famciclovir, which belongs to a group of medicines called antiviral agents. These are medicines used in the treatment of infections caused by viruses

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Famciclovir 750mg Film-Coated Tablets outweigh the risks, hence a Marketing Authorisation has been granted.

**FAMCICLOVIR 750MG FILM-COATED TABLETS  
PL 00289/1089**

**SCIENTIFIC DISCUSSION**

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## **INTRODUCTION**

Based on the review of the data on quality, safety and efficacy, the MHRA granted a marketing authorisation for the medicinal product Famciclovir 750mg Film-Coated Tablets (PL 00289/1089) on 11th March 2009. The product is a prescription-only medicine for the treatment of *herpes zoster* (shingles) infections.

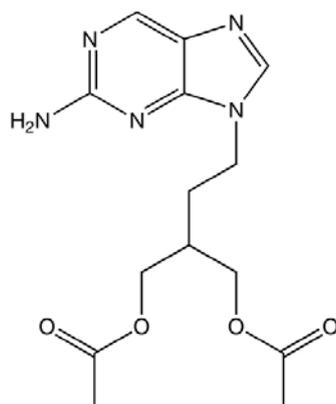
The application was submitted as an abridged application according to Article 10.1 of Directive 2001/83/EC, as amended, claiming essential similarity to the original product Famvir Tablets 750mg (Novartis Pharmaceuticals UK Limited), which was originally granted to Smithkline Beecham in 1996.

Famciclovir is the oral pro-drug of penciclovir. It is rapidly converted *in vivo* to penciclovir, which has *in vivo* and *in vitro* activity against human herpes viruses (including *varicella zoster* and *herpes simplex* types 1 and 2). Penciclovir inhibits herpes virus DNA replication once it has been phosphorylated to the active triphosphate form by virus-induced thymidine kinase, which is only present in virus-infected cells.

## PHARMACEUTICAL ASSESSMENT

### ACTIVE SUBSTANCE

INN: Famciclovir  
Chemical Name: 2-[2-(2-Amino-9H-purin-9-yl)ethyl]-1,3-propanediol diacetate (ester)  
9-[4-acetoxy-3-(acetoxymethyl)but-1-yl]-2-aminopurine  
Molecular Formula: C<sub>14</sub>H<sub>19</sub>N<sub>5</sub>O<sub>4</sub>  
Structure:



Molecular Weight: 321.34  
Appearance: White to pale yellow (or off-white) solid, freely soluble in water, methanol and acetate, and sparingly soluble in ethanol and propan-1-ol.  
Polymorphism: Famciclovir is known to exist in four crystal forms.

Appropriate methods of manufacture have been provided for famciclovir. Appropriate in-process controls are in place to ensure consistency between batches.

Appropriate specifications are provided by both active substance manufacturers for active famciclovir. The analytical methods are suitable and satisfactory validation data have been provided. All reference standards used have been sufficiently characterised and certificates of analysis provided. Batch analysis data have been provided for famciclovir and show compliance with the active substance specifications.

Satisfactory specifications have been provided for all packaging components. The primary packaging has been shown to comply with current legislation concerning the use of materials in contact with foodstuff.

An appropriate retest period has been stated for the active, based on stability data submitted.

## **DRUG PRODUCT**

### **Excipients**

Other ingredients consist of microcrystalline cellulose E460, colloidal anhydrous silica E551, sodium starch glycolate (Type A), low-substituted hydroxypropylcellulose, croscarmellose sodium, sodium stearyl fumarate, titanium dioxide E171, polydextrose E1200, hypromellose E464, triacetin E1518 and macrogol 8000.

With the exception of polydextrose E1200, microcrystalline cellulose E460 and low-substituted hydroxypropylcellulose, all excipients comply with their respective European Pharmacopoeia monographs. Polydextrose E1200 and low-substituted hydroxypropylcellulose comply with suitable in-house specifications.

Microcrystalline cellulose E460 is composed of microcrystalline cellulose and 2% w/w colloidal anhydrous silica, both of which comply with their respective European Pharmacopoeia monographs.

Suitable certificates of analysis have been provided for all excipients, showing compliance with the proposed specifications.

None of the excipients is derived from materials of animal or human origin. No genetically modified materials are used in the manufacture of any of the excipients.

### **Container-closure system**

The product is packaged in polyvinylchloride/polyethylene/aclear-aluminium blister packs in pack sizes of 1, 7 and 50 tablets. Suitable specifications and certificates of analysis have been provided for the finished packaging. All packaging components comply with relevant guidelines concerning contact with foodstuff.

### **Product development**

The objective of the product development programme was to produce a tolerable product with the same efficacy as that for the reference product Famvir Tablets 750mg (Novartis Pharmaceuticals UK Limited).

A satisfactory pharmaceutical development section has been provided. The rationale and function of each excipient added is discussed. Levels of each ingredient are typical for a product of this nature and have been optimised on the basis of results from development studies.

Comparative dissolution profiles have been provided for the finished product versus the reference product.

### **Manufacture**

A satisfactory batch formula has been provided for the manufacture of the product along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results.

### **Finished product specification**

The tablets are white to off-white, oval, film-coated tablets, engraved 8120 on one side and 93 on the other side.

The finished product specifications proposed for both release and shelf-life are acceptable, and provide an assurance of the quality and consistency of the finished product. The analytical methods used have been suitably validated. Batch analysis data has demonstrated compliance with the proposed release specification.

**Stability of the product**

Stability data has been provided for batches of the finished product stored in-line with ICH guidelines. All batches were manufactured by the finished product manufacturer, according to the proposed manufacturing method and stored in the packaging proposed for marketing.

Based on these stability studies, a shelf-life of 3 years has been proposed with storage conditions of “Keep blister in the outer carton in order to protect from light”. These are acceptable.

**SPC, PIL, Labels**

The SPC, PIL and labels are pharmaceutically acceptable.

**Pharmaceutical expert report**

The pharmaceutical expert report has been written by an appropriately qualified person and is a suitable summary of the pharmaceutical aspects of the dossier.

**CONCLUSION**

It is recommended that a Marketing Authorisation is granted for this application.

## **PRECLINICAL ASSESSMENT**

This application is for a generic product, claiming to be a generic medicinal product of Famvir Tablets 750mg (Novartis Pharmaceuticals UK Limited), which have been licensed within the EEA for over 10 years.

No new preclinical data have been supplied with this application and none are required for an application of this type. A preclinical expert report has been written by an appropriately qualified person. It is a suitable summary of the preclinical aspects of the dossier.

## CLINICAL ASSESSMENT

### CLINICAL PHARMACOLOGY

With the exception of the bioequivalence study, no new clinical pharmacology data have been submitted with this application and none are required.

The following bioequivalence study was submitted:

A single-dose, randomised, two-sequence, two-period, crossover study comparing Famciclovir 250mg Film-Coated Tablets versus Famvir 250mg Tablets (Novartis Pharmaceuticals UK Limited), administered as 2x250mg tablets in healthy volunteers under fasted conditions.

Blood samples were taken pre- and up to 16 hours post dose to measure the concentrations of the active metabolite penciclovir. The two study periods were separated by a washout period of 7 days.

The results are presented below as geometric means based on least-squares means of log-transformed data:

Parameter	Test Prod Famciclovir 2x250mg Film- Coated Tablets	Reference Prod Famvir 2x250mg Film-Coated Tablets	90% CI Point Est (Range)
$C_{max}$ (ng/ml)	3841.82	3955.82	89.0 – 106.0
$AUC_{(0-t)}$ $\mu\text{g}^*\text{h}/\text{ml}$	9983.32	10 027.21	96.2 – 103.0
$AUC_{(0-\infty)}$ $\mu\text{g}^*\text{h}/\text{ml}$	10 096.01	10 140.66	96.3 – 103.0

The 90% confidence intervals for active metabolite penciclovir lie within the acceptance criteria specified in the Note for Guidance on the Investigation of Bioavailability and Bioequivalence (CPMP/EWP/QWP/1401/98) and the test product can be considered bioequivalent to the reference product.

As products manufactured using active famciclovir meet all the criteria as specified in the Note for Guidance on the Investigation of Bioavailability and Bioequivalence (CPMP/EWP/QWP/1401/98), the results and conclusions of this bioequivalence study can be extrapolated to the 750mg strength tablets also.

### CLINICAL EFFICACY

No new clinical efficacy data have been provided and none are required for an application of this type.

### CLINICAL SAFETY

No new clinical safety data were submitted for this application and one are required.

### CLINICAL EXPERT REPORT

The clinical expert report has been written by an appropriately qualified physician. It is an appropriate summary of the clinical aspects of the dossier.

### PRODUCT LITERATURE

#### Summary of Product Characteristics (SPC)

The SPC is satisfactory and consistent with that for the reference product, where appropriate.

**Patient Information Leaflet (PIL)**

The PIL is satisfactory and consistent with that for the reference product, where appropriate.

**Labels**

The labels are appropriate for a product of this nature.

**CONCLUSIONS**

The safety and efficacy of famciclovir have been well-established. The applicant has demonstrated the bioequivalence of this product with the reference product (Famvir Tablets 750mg) in an appropriately conducted study.

The grant of a marketing authorisation is recommended.

## OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

### QUALITY

The important quality characteristics of Famciclovir 750mg Film-Coated Tablets are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

### PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

### EFFICACY

Bioequivalence has been demonstrated between the applicant's Famciclovir 750mg Film-Coated Tablets and the reference product Famvir Tablets 750mg (Novartis Pharmaceuticals UK Limited).

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with that for Famvir 750mg Tablets.

### RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The bioequivalence study supports the claim that the applicant's products and the innovator products are interchangeable. Extensive clinical experience with famciclovir is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.

**FAMCICLOVIR 750MG FILM-COATED TABLETS  
PL 00289/1089**

**STEPS TAKEN FOR ASSESMENT**

1	The MHRA received the marketing authorisation application on 3 <sup>rd</sup> August 2007
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 22 <sup>nd</sup> October 2007
3	Following assessment of the application, the MHRA requested further information relating to the quality dossiers on 2 <sup>nd</sup> September 2008 and 30 <sup>th</sup> January 2009. No requests for further information were made for the clinical dossiers.
4	The applicant responded to the MHRA's requests, providing further information for the quality dossier on 14 <sup>th</sup> October 2008 and 19 <sup>th</sup> February 2009
5	The application was determined on 11 <sup>th</sup> March 2009

**FAMCICLOVIR 750MG FILM-COATED TABLETS  
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**STEPS TAKEN AFTER AUTHORISATION - SUMMARY**

<b>Date submitted</b>	<b>Application type</b>	<b>Scope</b>	<b>Outcome</b>

## SUMMARY OF PRODUCT CHARACTERISTICS

### 1 NAME OF THE MEDICINAL PRODUCT

Famciclovir 750 mg Film-coated Tablets

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 750 mg famciclovir.

For a full list of excipients, see section 6.1.

### 3 PHARMACEUTICAL FORM

Film-coated tablet.

White to off-white, oval, film-coated tablets, engraved 8120 on one side and 93 on the other side.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

For the treatment of herpes zoster (shingles) infections.

#### 4.2 Posology and method of administration

##### Dosage

##### *Adults*

One 750 mg tablet once daily for seven days.

The tablet should be taken at approximately the same time each day.

Initiation of treatment is recommended as soon as possible after rash onset.

##### *Elderly*

Dosage modification is not required unless renal function is impaired.

##### *Renally impaired*

The 750 mg strength is not appropriate under these circumstances. Other strengths are available.

##### *Hepatically impaired*

Dosage modification is not required for patients with well compensated chronic liver disease. There is no information on patients with decompensated chronic liver disease; accordingly no precise dose recommendations can be made for this group of patients.

##### *Children*

There are currently insufficient data on the safety and efficacy of famciclovir in children and therefore its use in children is not recommended.

##### Administration

Oral

#### 4.3 Contraindications

Hypersensitivity to famciclovir or to any of the excipients.

Hypersensitivity to penciclovir.

#### 4.4 Special warnings and precautions for use

Special attention should be paid to patients with impaired renal function as dosage adjustment is necessary (see sections 4.2 and 4.9). No special precautions are required for hepatically impaired or elderly patients with normal renal function.

#### 4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions have been identified. Evidence from preclinical studies has shown no potential for induction of cytochrome P450. Probenecid and other substances that affect renal physiology could affect plasma levels of penciclovir. In a Phase I study, no interactions were observed after co-administration of zidovudine and famciclovir.

**4.6 Pregnancy and lactation**

Although animal studies have not shown any embryotoxic or teratogenic effects with famciclovir or penciclovir, the safety of famciclovir in human pregnancy has not been established. It should therefore not be used during pregnancy or in nursing mothers unless the potential benefits of treatment outweigh any possible risk.

Studies in rats show that penciclovir is excreted in the milk of lactating females given oral famciclovir. There is no information on excretion in human milk.

**4.7 Effects on ability to drive and use machines**

Patients who experience dizziness, somnolence, confusion or other central nervous system disturbances while taking famciclovir should refrain from driving or operating machinery.

**4.8 Undesirable effects**

Headache and nausea have been reported in clinical trials. These were generally mild or moderate in nature and occurred at a similar incidence in patients receiving placebo treatment.

The following table specifies the estimated frequency of adverse reactions based on all the spontaneous reports and literature cases that have been reported for famciclovir since its introduction to the market.

Frequencies are defined as common ( $>1/100, \leq 1/10$ ), uncommon ( $>1/1000, \leq 1/100$ ), rare ( $>1/10000, \leq 1/1000$ ), very rare ( $<1/10000$ ).

Nervous system disorders	
Rare	Headache, confusion (predominantly in the elderly)
Very rare	Dizziness, somnolence (predominantly in the elderly), hallucinations
Gastrointestinal disorders	
Rare	Nausea
Very rare	Vomiting
Hepato-biliary disorders	
Very rare	Jaundice
Skin and subcutaneous tissue disorders	
Very rare	Rash, pruritus, urticaria

**4.9 Overdose**

Overdose experience with famciclovir is limited. A report of accidental acute overdose (10.5 g) was asymptomatic. In a report of chronic use (10 g/day for two years), famciclovir was well tolerated. In the event of an overdose supportive and symptomatic therapy should be given as appropriate.

Acute renal failure has been reported rarely in patients with underlying renal disease where the famciclovir dose has not been appropriately reduced for the level of renal function.

Penciclovir is dialysable and plasma concentrations are reduced by approximately 75% following four hours' haemodialysis.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmaco-therapeutic group: [Nucleosides and nucleotides excl. reverse transcriptase inhibitors](#)

ATC code: J05A B09

Famciclovir is the oral form of penciclovir. Famciclovir is rapidly converted *in vivo* into penciclovir, which has *in vivo* and *in vitro* activity against human herpes viruses including varicella zoster virus and herpes simplex types 1 and 2.

The antiviral effect of orally administered famciclovir has been demonstrated in several animal models; this effect is due to *in vivo* conversion to penciclovir. In virus-infected cells penciclovir is rapidly and efficiently converted into the triphosphate (mediated via virus-induced thymidine kinase). Penciclovir triphosphate persists in infected cells for more than 12 hours where it inhibits replication of viral DNA and has a half-life of 9, 10 and 20 hours in cells infected with varicella zoster, herpes simplex virus type 1 and herpes simplex virus type 2, respectively. In uninfected cells treated with penciclovir, concentrations of penciclovir-triphosphate are only barely detectable. Accordingly, uninfected cells are unlikely to be affected by therapeutic concentrations of penciclovir.

The most common form of resistance encountered with aciclovir among HSV strains is a deficiency in the production of the thymidine kinase (TK) enzyme. Such TK-deficient strains would be expected to be cross-resistant to both penciclovir and aciclovir. However, penciclovir has been shown to be active *in vitro* against a recently isolated aciclovir-resistant herpes simplex virus strain which has an altered DNA polymerase.

### 5.2 Pharmacokinetic properties

#### General characteristics

Following oral administration, famciclovir is rapidly and extensively absorbed and rapidly converted to the active compound, penciclovir. Bioavailability of penciclovir after oral administration of famciclovir is 77%. Mean peak plasma concentrations of penciclovir, following 125 mg, 250 mg and 500 mg oral doses of famciclovir, were 0.8 micrograms/ml, 1.6 micrograms/ml and 3.3 micrograms/ml, respectively, and occurred at a median time of 45 minutes post-dose. Plasma concentration-time curves of penciclovir are similar following single and repeat (two and three times daily) dosing. The terminal plasma half-life of penciclovir after both single and repeat dosing with famciclovir is approximately 2.0 hours. There is no accumulation of penciclovir on repeated dosing with famciclovir. Penciclovir and its 6-deoxy precursor are poorly (<20%) bound to plasma proteins.

Famciclovir is eliminated principally as penciclovir and its 6-deoxy precursor which are excreted in urine unchanged. Famciclovir has not been detected in urine. Tubular secretion contributes to the renal elimination of the compound.

#### Characteristics in patients

Uncomplicated herpes zoster infection does not significantly alter the pharmacokinetics of penciclovir measured after oral administration of famciclovir.

### 5.3 Preclinical safety data

Famciclovir has no significant effects on spermatogenesis or sperm morphology and motility in man. At doses greatly in excess of those used therapeutically impaired fertility was observed in male rats - no such effects being observed in female rats.

At a dose level approximately 50 times the normal therapeutic dose there was an increased incidence of mammary adenocarcinoma in female rats. No such effect was seen in male rats or mice of either sex.

Additionally, famciclovir was not found to be genotoxic in a comprehensive battery of *in vivo* and *in vitro* tests designed to detect gene mutation, chromosomal damage and repairable damage to DNA.

Penciclovir, in common with other drugs of this class, has been shown to cause chromosomal damage, but did not induce gene mutation in bacterial or mammalian cell systems, nor was there evidence of increased DNA repair *in vitro*.

These findings are not considered to have any clinical significance.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

*Core:*

Microcrystalline cellulose E460  
Colloidal anhydrous silica E551  
Sodium starch glycolate (Type A)  
Low-substituted hydroxypropylcellulose  
Croscarmellose sodium  
Sodium stearyl fumarate

*Film-coat:*

Titanium dioxide E 171  
Polydextrose E1200  
Hypromellose E464  
Triacetin E1518  
Macrogol 8000

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years.

### **6.4 Special precautions for storage**

Keep blister in the outer carton in order to protect from light.

### **6.5 Nature and contents of container**

White opaque PVC/PE/Aclar – Aluminium blisters packs  
1 & 7 film-coated tablets. Hospital packs of 50 (50 x 1) film-coated tablets  
Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

TEVA UK Limited, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG,  
United Kingdom

## **8 MARKETING AUTHORISATION NUMBER(S)**

PL 00289/1089

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

11/03/2009

## **10 DATE OF REVISION OF THE TEXT**

11/03/2009

## PATIENT INFORMATION LEAFLET (PIL)

### FAMCICLOVIR 750 mg FILM-COATED TABLETS

#### PACKAGE LEAFLET: INFORMATION FOR THE USER

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 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 take Famciclovir 750 mg Film-Coated Tablets
3. How to take Famciclovir 750 mg Film-Coated Tablets
4. Possible side effects
5. How to store Famciclovir 750 mg Film-Coated Tablets
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 750 mg Film-Coated Tablets are used to treat infections caused by the *herpes zoster* virus, which causes shingles.

### 2 BEFORE YOU TAKE FAMCICLOVIR 750 mg FILM-COATED TABLETS

Do NOT take Famciclovir 750 mg Film-Coated Tablets

- if you are allergic (hypersensitive) to famciclovir or penciclovir (if you develop a rash or other signs of allergy (hypersensitivity))
- if you are allergic (hypersensitive) to one or more of the other ingredients of your medicine. These other ingredients are mentioned in section '6. Further information' of this leaflet. Allergic reactions can be identified for example by the appearance of a rash, itching, or a swollen face.

Take special care with Famciclovir 750 mg Film-Coated Tablets

- Tell your doctor if you have kidney problems, as he/she may need to prescribe a different dose.

#### Taking other medicines

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 acetyl salicylic acid and ibuprofen.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines

obtained without a prescription.

#### Taking Famciclovir 750 mg Film-Coated Tablets with food and drink

You should swallow your tablet whole with water. You can take it before or during meals.

#### Pregnancy and breast-feeding

It is not known if it is safe to use famciclovir during pregnancy and breast-feeding. You should not use famciclovir if you are pregnant unless your doctor specifically tells you to. You should not use famciclovir if you are breast-feeding.

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

#### Driving and using machines

Famciclovir may cause dizziness, drowsiness and confusion in rare cases. If you experience one of these symptoms during treatment with this medicine you should take extra care when driving or operating machines.

### 3 HOW TO TAKE FAMCICLOVIR 750 mg FILM-COATED TABLETS

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

Take Famciclovir for the prescribed period, in the prescribed manner, and at the prescribed times. Do not stop the treatment even if you feel better after a few days, unless your doctor advises you otherwise.

The usual dose is one tablet once a day, for 7 days. 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. Other strengths are available if the dose is not practicable with the 750 mg tablets.

#### Elderly patients

Your doctor may need to adjust the dose of famciclovir you must take depending on your kidney function.

#### Children

Famciclovir is not recommended in children as there is no experience on its use in children.

Please consult your doctor or pharmacist if you find that the effect of famciclovir is too great or too weak.

#### If you take more famciclovir than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Please take this leaflet, any remaining tablets and the container with you to the

hospital or doctor so that they know which tablets were consumed.

#### If you forget to take famciclovir

If you have forgotten to take a tablet, then take this tablet as soon as possible. Take the next tablet at the usual time; however, if it is almost time for the next tablet, do not take the tablet you have skipped. Continue by taking the next tablet at the usual time.

Do not take a double dose of famciclovir to make up for a forgotten dose. If you have any questions about this please consult your doctor.

#### If you stop taking famciclovir

In general, you should not stop the treatment on your own, without consulting your doctor.

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:

**Rare (affecting fewer than one person in 1,000 but more than one person in 10,000):**

- Headache
- confusion (predominantly in the elderly)
- Nausea.

**Very rare (affecting fewer than one person in 10,000):**

- Hallucinations
- Dizziness
- Drowsiness (predominantly in the elderly)
- Vomiting
- Yellowing of the skin and eyes (jaundice)
- Rash, including nettle rash (hives), itching.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

### 5 HOW TO STORE FAMCICLOVIR 750 mg FILM-COATED TABLETS

Keep out of the reach and sight of children.

Do not use Famciclovir 750 mg Film-Coated Tablets after the expiry date which is stated on the packaging after "exp" on the box or blister pack. The expiry date refers to the last day of the month.

Keep the blister in the outer carton in order to protect from light.

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 750 mg Film-Coated Tablets contain**

- The active ingredient is famciclovir. Each film-coated tablet contains 750 mg famciclovir.
- The other ingredients are

microcrystalline cellulose E460, sodium starch glycolate (Type A), colloidal anhydrous silica E551, low substituted hydroxypropylcellulose, croscarmellose sodium, sodium stearyl fumarate, titanium dioxide E171, polydextrose, hypromellose, triacetin and macrogol.

#### What Famciclovir 750 mg Film-Coated Tablets look like and contents of the pack

- Famciclovir 750 mg Film-Coated Tablets are white to off-white, oval, film-coated tablets, engraved 8120 on one side and 93 on the other side.
- They are available in white opaque PVC/PE/Aclar – Aluminium blisters. Pack sizes of 1 & 7 film-coated tablets. Hospital packs of 50 (50 x 1) film-coated tablets. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder and Manufacturer

TEVA UK Limited, Eastbourne, BN22 9AG.

This leaflet was last revised in March 2009

PL 00289/1089

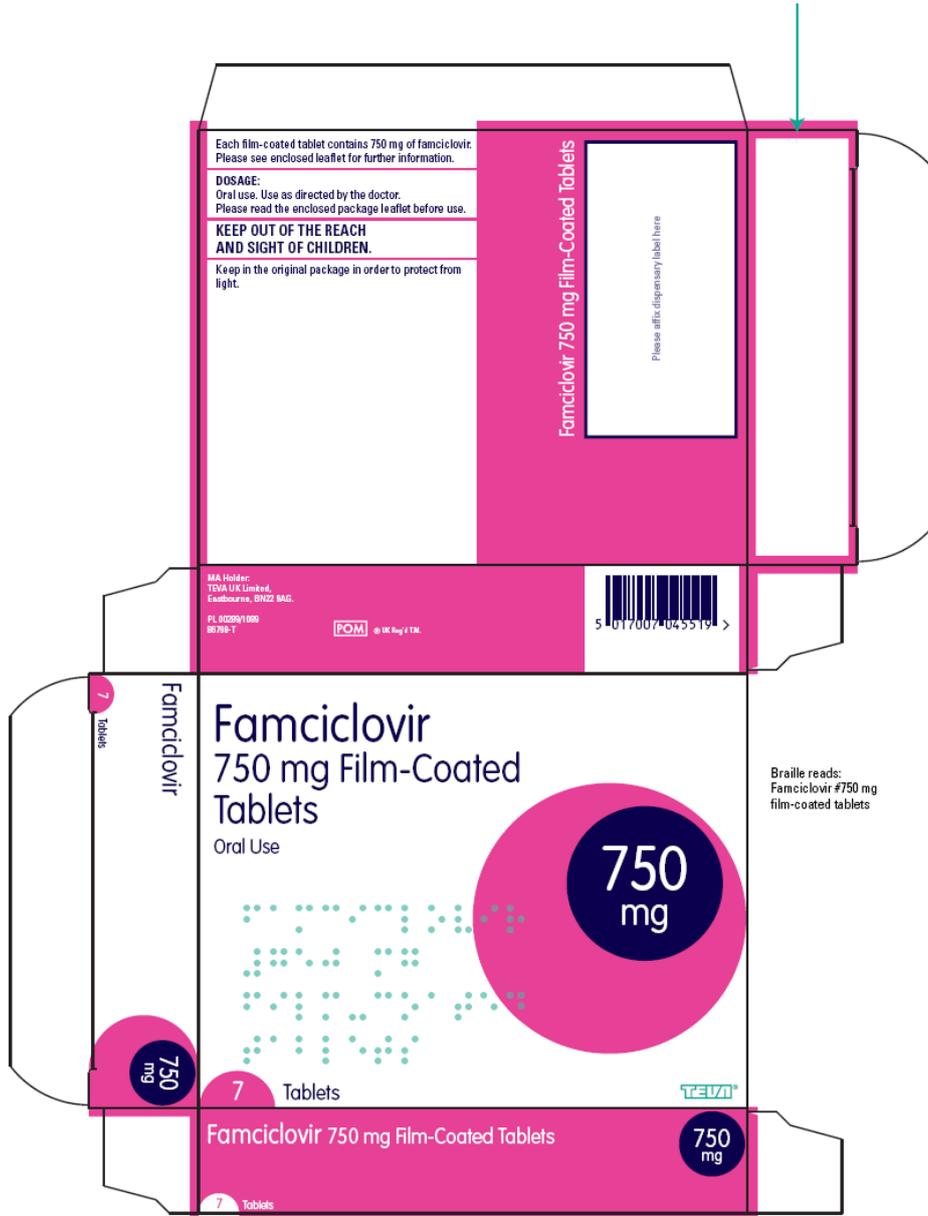


TEVA UK LIMITED

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PACKAGING



Famciclovir 750 mg Film-Coated Tablets MA Holder: TEVA UK Ltd 86929-T	Famciclovir 750 mg Film-Coated Tablets MA Holder: TEVA UK Ltd 86929-T	Famciclovir 750 mg Film-Coated MA Holder: TEVA UK 86929-T
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