SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Famvir and associated names (see Annex I) 125 mg film-coated tablets
Famvir and associated names (see Annex I) 250 mg film-coated tablets
Famvir and associated names (see Annex I) 500 mg film-coated tablets
[See Annex I - To be completed nationally]

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[To be completed nationally]

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet
[To be completed nationally]

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Varicella zoster virus (VZV) infections – herpes zoster
Famvir is indicated for

- the treatment of herpes zoster and ophthalmic zoster in immunocompetent adults (see section 4.4)
- the treatment of herpes zoster in immunocompromised adults (see section 4.4)

Herpes simplex virus (HSV) infections – genital herpes
Famvir is indicated for

- the treatment of first and recurrent episodes of genital herpes in immunocompetent adults
- the treatment of recurrent episodes of genital herpes in immunocompromised adults
- the suppression of recurrent genital herpes in immunocompetent and immunocompromised adults

Clinical studies have not been conducted in HSV-infected patients immunocompromised for other causes than HIV-infection (see section 5.1).

4.2 Posology and method of administration

Herpes zoster in immunocompetent adults

500 mg three times daily for seven days.

Treatment should be initiated as soon as possible after a diagnosis of herpes zoster.

Herpes zoster in immunocompromised adults

500 mg three times daily for ten days.

Treatment should be initiated as soon as possible after a diagnosis of herpes zoster.

Genital herpes in immunocompetent adults

First episode of genital herpes: 250 mg three times daily for five days. Initiation of treatment is recommended as soon as possible after a diagnosis of first episode of genital herpes.

Episodic treatment of recurrent genital herpes: 125 mg twice daily for five days. Initiation of treatment is recommended as soon as possible after onset of prodromal symptoms (e.g. tingling, itching, burning, pain) or lesions.

Recurrent genital herpes in immunocompromised adults

Episodic treatment of recurrent genital herpes: 500 mg twice daily for seven days. Initiation of treatment is recommended as soon as possible after onset of prodromal symptoms (e.g. tingling, itching, burning, pain) or lesions.

Suppression of recurrent genital herpes in immunocompetent adults

250 mg twice daily. Suppressive therapy should be discontinued after a maximum of 12 months of continuous antiviral therapy to reassess recurrence frequency and severity. The minimum period of reassessment should include two recurrences. Patients who continue to have significant disease may restart suppressive therapy.

Suppression of recurrent genital herpes in immunocompromised adults

500 mg twice daily.

Patients with renal impairment

Because reduced clearance of penciclovir is related to reduced renal function, as measured by creatinine clearance, special attention should be given to doses in patients with impaired renal function. Dose recommendations for adult patients with renal impairment are provided in Table 1.

Table 1 Dose recommendations for adult patients with renal impairment

Indication and nominal dose regimen	**Creatinine clearance [ml/min]**	**Adjusted dose regimen**
Herpes zoster in immunocompetent adults		
500 mg three times daily for 7 days	≥ 60	500 mg three times daily for 7 days
	40 to 59	500 mg twice daily for 7 days
	20 to 39	500 mg once daily for 7 days
	< 20	250 mg once daily for 7 days
	Haemodialysis patients	250 mg following each dialysis during 7 days
Herpes zoster in immunocompromised adults		
500 mg three times daily for 10 days	≥ 60	500 mg three times daily for 10 days
	40 to 59	500 mg twice daily for 10 days
	20 to 39	500 mg once daily for 10 days
	< 20	250 mg once daily for 10 days
	Haemodialysis patients	250 mg following each dialysis during 10 days
Genital herpes in immunocompetent adults – first episode of genital herpes		
250 mg three times daily for 5 days	≥ 40	250 mg three times daily for 5 days
	20 to 39	250 mg twice daily for 5 days
	< 20	250 mg once daily for 5 days
	Haemodialysis patients	250 mg following each dialysis during 5 days

Genital herpes in immunocompetent adults – episodic treatment of recurrent genital herpes		
125 mg twice daily for 5 days	≥ 20	125 mg twice daily for 5 days
	< 20	125 mg once daily for 5 days
	Haemodialysis patients	125 mg following each dialysis during 5 days
Genital herpes in immunocompromised adults – episodic treatment of recurrent genital herpes		
500 mg twice daily for 7 days	≥ 40	500 mg twice daily for 7 days
	20 to 39	500 mg once daily for 7 days
	< 20	250 mg once daily for 7 days
	Haemodialysis patients	250 mg following each dialysis during 7 days
Suppression of recurrent genital herpes in immunocompetent adults		
250 mg twice daily	≥ 40	250 mg twice daily
	20 to 39	125 mg twice daily
	< 20	125 mg once daily
	Haemodialysis patients	125 mg following each dialysis
Suppression of recurrent genital herpes in immunocompromised adults		
500 mg twice daily	≥ 40	500 mg twice daily
	20 to 39	500 mg once daily
	< 20	250 mg once daily
	Haemodialysis patients	250 mg following each dialysis

Patients with renal impairment on haemodialysis
Since 4 h haemodialysis resulted in up to 75% reduction in plasma penciclovir concentrations, famciclovir should be administered immediately following dialysis. The recommended dose regimens for haemodialysis patients are included in Table 1.

Patients with hepatic impairment
No dose adjustment is required in patients with mild or moderate hepatic impairment. No data are available for patients with severe hepatic impairment (see sections 4.4 and 5.2).

Elderly patients (≥ 65 years)
Dose modification is not required unless renal function is impaired.

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

Method of administration
Famvir can be taken without regard to meals (see section 5.2).

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.
Hypersensitivity to penciclovir.

4.4 Special warnings and precautions for use

Use in patients with renal impairment
In patients with impaired renal function dose adjustment is necessary (see sections 4.2 and 4.9).

Use in patients with hepatic impairment
Famciclovir has not been studied in patients with severe hepatic impairment. Conversion of famciclovir to its active metabolite penciclovir may be impaired in these patients resulting in lower penciclovir plasma concentrations, and thus a decrease of efficacy of famciclovir may occur.

Use for zoster treatment
Clinical response should be closely monitored, particularly in immunocompromised patients. Consideration should be given to intravenous antiviral therapy when response to oral therapy is considered insufficient.
Patients with complicated herpes zoster, i.e. those with visceral involvement, disseminated zoster, motor neuropathies, encephalitis and cerebrovascular complications should be treated with intravenous antiviral therapy.
Moreover, immunocompromised patients with ophthalmic zoster or those with a high risk for disease dissemination and visceral organ involvement should be treated with intravenous antiviral therapy.

Transmission of genital herpes
Patients should be advised to avoid intercourse when symptoms are present even if treatment with an antiviral has been initiated. During suppressive treatment with antiviral agents, the frequency of viral shedding is significantly reduced. However, transmission is still possible. Therefore, in addition to therapy with famciclovir, it is recommended that patients use safer sex practices.

Other
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

4.5 Interaction with other medicinal products and other forms of interaction

Effects of other medicinal products on famciclovir
No clinically significant interactions have been identified.

Concurrent use of probenecid may result in increased plasma concentrations of penciclovir, the active metabolite of famciclovir, by competing for elimination.
Therefore, patients receiving famciclovir at a dose of 500 mg three times daily co-administered with probenecid, should be monitored for toxicity. If patients experience severe dizziness, somnolence, confusion or other central nervous system disturbances, a dose reduction of famciclovir to 250 mg three times daily may be considered.

Famciclovir needs aldehyde oxidase to be converted into penciclovir, its active metabolite. Raloxifen has been shown to be a potent inhibitor of this enzyme in vitro. Co-administration of raloxifene could affect the formation of penciclovir and thus the efficacy of famciclovir. When raloxifen is co-administered with famciclovir the clinical efficacy of the antiviral therapy should be monitored.

4.6 Pregnancy and lactation

Pregnancy
There is a limited amount of data (less than 300 pregnancy outcomes) from the use of famciclovir in pregnant women. Based on these limited amounts of information, the cumulative analysis of both prospective and retrospective pregnancy cases did not provide evidence indicating that the product causes any specific foetal defect or congenital anomaly. Animal studies have not shown any embryotoxic

or teratogenic effects with famciclovir or penciclovir (the active metabolite of famciclovir). Famciclovir should only be used during pregnancy when the potential benefits of treatment outweigh the potential risks.

Lactation
It is unknown whether famciclovir is excreted in human breast milk. Animal studies have shown excretion of penciclovir in breast milk. If the woman's condition mandates treatment with famciclovir, discontinuation of breast-feeding may be considered.

Fertility
Clinical data do not indicate an impact of famciclovir on male fertility following long-term treatment at an oral dose of 250 mg twice daily (see section 5.3).

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, patients who experience dizziness, somnolence, confusion or other central nervous system disturbances while taking Famvir should refrain from driving or operating machinery.

4.8 Undesirable effects

Headache and nausea have been reported in clinical studies. These were generally mild or moderate in nature and occurred at a similar incidence in patients receiving placebo treatment. All other adverse reactions were added during postmarketing.

A total of 1,587 patients have received famciclovir at recommended doses in placebo- (n= 657) and active- (n=930) controlled studies. These clinical studies were retrospectively reviewed to obtain a frequency category for all adverse reactions mentioned below. For adverse reactions which have never been observed in these studies, the upper limit of the 95% confidence interval is not expected to be higher than 3/X (based on the "rule of three"), with X representing the total sample size (n=1,587).

Adverse reactions (Table 2) are ranked under headings of frequency, using the following convention: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000).

Table 2 Adverse reactions

Blood and lymphatic system disorders		
	Rare:	Thrombocytopenia.
Psychiatric disorders		
	Uncommon:	Confusion
	Rare:	Hallucinations.
Nervous system disorders		
	Very common:	Headache
	Common:	Dizziness, somnolence
Gastrointestinal disorders		
	Common:	Nausea, vomiting.
	Rare:	~~Vomiting~~.
Hepatobiliary disorders		
	Common:	Abnormal liver function tests
	Rare:	Cholestatic jaundice.
Skin and subcutaneous tissue disorders		
	Common:	Rash, pruritus
	Uncommon:	Urticaria, serious skin reactions* (e.g. erythema multiforme, Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis)

** Never reported in clinical trials; category is based on the "rule of three"*

Overall, adverse reactions reported from clinical studies with immunocompromised patients were similar to those reported in the immunocompetent population. Nausea, vomiting and abnormal liver function tests were reported more frequently, especially at higher doses.

4.9 Overdose

Overdose experience with famciclovir is limited. 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; plasma concentrations are reduced by approximately 75% following 4 h haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Nucleosides and nucleotides excluding reverse transcriptase inhibitors, ATC code: JO5AB09

Mechanism of action
Famciclovir is the oral prodrug of penciclovir. Famciclovir is rapidly converted *in vivo* into penciclovir, which has *in vitro* activity against herpes simplex viruses (HSV types 1 and 2), varicella zoster virus, Epstein-Barr virus and cytomegalovirus.

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 the viral thymidine kinase (TK) phosphorylates penciclovir to a monophosphate form that, in turn, is converted to penciclovir triphosphate by cellular kinases. This triphosphate persists in infected cells in excess of 12 hours and inhibits viral DNA chain elongation by competitive inhibition with deoxyguanosine triphosphate for incorporation into the growing viral DNA, thus halting virus replication of viral DNA. In uninfected cells treated with penciclovir, concentrations of penciclovir-triphosphate are only barely detectable. Hence the probability of toxicity to mammalian host cells is low and uninfected cells are unlikely to be affected by therapeutic concentrations of penciclovir.

Resistance
Like aciclovir, the most common form of resistance encountered among HSV strains is a deficiency in the production of the thymidine kinase (TK) enzyme. Such TK deficient strains would generally be expected to be cross-resistant to both penciclovir and aciclovir.

Results from 11 worldwide clinical studies involving penciclovir (topical or intravenous formulations) or famciclovir in immunocompetent or immunocompromised patients, including studies of up to 12 months treatment with famciclovir, have shown a small overall frequency of penciclovir resistant isolates: 0.2% (2/913) in immunocompetent patients and 2.1% (6/288) in immunocompromised patients. The resistant isolates were mostly found at the start of treatment or in a placebo group, with resistance occurring on or after treatment with famciclovir or penciclovir only in two immunocompromised patients.

Clinical efficacy
In placebo-controlled and active-controlled studies both in immunocompetent and immunocompromised patients with uncomplicated herpes zoster, famciclovir was effective in the resolution of lesions. In an-active-controlled clinical study, famciclovir was shown to be effective in the treatment of ophthalmic zoster in immunocompetent patients.

Efficacy of famciclovir in immunocompetent patients with first episode of genital herpes was shown in three active-controlled studies**.** Two placebo-controlled studies in immunocompetent patients and

one-active controlled study in HIV-infected patients with recurrent genital herpes showed that famciclovir was effective.

Two placebo-controlled 12-month studies in immunocompetent patients with recurrent genital herpes showed that famciclovir-treated patients had a significant reduction of recurrences as compared to placebo-treated patients. Placebo-controlled and uncontrolled studies of up to 16 weeks duration showed that famciclovir was effective in the suppression of recurrent genital herpes in HIV-infected patients; the placebo-controlled study showed that famciclovir significantly decreased the proportion of days of both symptomatic and asymptomatic HSV shedding.

5.2 Pharmacokinetic properties

General characteristics

Absorption
Famciclovir is the oral prodrug of the antivirally active compound penciclovir. Following oral administration, famciclovir is rapidly and extensively absorbed and converted to penciclovir. Bioavailability of penciclovir after oral administration of famciclovir was 77%. Mean peak plasma concentration of penciclovir, following a 125 mg, 250 mg, 500 mg and 750 mg oral dose of famciclovir, was 0.8 microgram/ml, 1.6 micrograms/ml, 3.3 micrograms/ml and 5.1 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 (t.i.d. and b.i.d.) dosing, indicating that there is no accumulation of penciclovir on repeated dosing with famciclovir.

The extent of systemic availability (AUC) of penciclovir from oral famciclovir is unaffected by food.

Distribution
Penciclovir and its 6-deoxy precursor are poorly (< 20%) bound to plasma proteins.

Metabolism and elimination
Famciclovir is eliminated principally as penciclovir and its 6-deoxy precursor, which are excreted in urine. No unchanged famciclovir has been detected in urine. Tubular secretion contributes to the renal elimination of penciclovir.

The terminal plasma half-life of penciclovir after both single and repeat dosing with famciclovir was approximately 2 hours.

Evidence from preclinical studies has shown no potential for induction of cytochrome P450 enzymes and inhibition of CYP3A4.

Characteristics in special populations
Patients with herpes zoster infection
Uncomplicated herpes zoster infection does not significantly alter the pharmacokinetics of penciclovir measured after the oral administration of famciclovir. The terminal plasma half-life of penciclovir in patients with herpes zoster was 2.8 h and 2.7 h, respectively, after single and repeated dosing of famciclovir.

Subjects with renal impairment
The apparent plasma clearance, renal clearance, and plasma elimination rate constant of penciclovir decreased linearly with reductions in renal function, both after single and repeated dosing. Dose adjustment is necessary in patients with renal impairment (see section 4.2).

Subjects with hepatic impairment
Mild and moderate hepatic impairment had no effect on the extent of systemic availability of penciclovir following oral administration of famciclovir. No dose adjustment is recommended for patients with mild and moderate hepatic impairment (see sections 4.2 and 4.4). The pharmacokinetics of penciclovir have not been evaluated in patients with severe hepatic impairment. Conversion of

famciclovir to the active metabolite penciclovir may be impaired in these patients resulting in lower penciclovir plasma concentrations, and thus possibly a decrease of efficacy of famciclovir.

Elderly patients (≥ 65 years)
Based on cross-study comparisons, the mean penciclovir AUC was about 30% higher and penciclovir renal clearance about 20% lower after oral administration of famciclovir in elderly volunteers (65-79 years) compared to younger volunteers. Partly this difference may be due to differences in renal function between the two age groups. No dose adjustment based on age is recommended unless renal function is impaired (see section 4.2).

Gender
Small differences in renal clearance of penciclovir between females and males have been reported and were attributed to gender differences in renal function. No dose adjustment based on gender is recommended.

5.3 Preclinical safety data

General toxicity
Studies on safety pharmacology and repeated dose toxicity reveal no special hazard for humans.

Genotoxicity
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 substances 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*.

Carcinogenicity
At high doses in female rats, there was an increased incidence of mammary adenocarcinoma, a tumour commonly observed in the strain of rats used in the carcinogenicity study. There was no effect on the incidence of neoplasia in male rats or in mice of either sex.

Reproductive toxicity
Impaired fertility (including histopathological changes in the testis, altered sperm morphology, reduced sperm concentration and motility, and reduced fertility) was observed in male rats given 500 mg/kg/day. Furthermore, degenerative changes of the testicular epithelium were noted in the general toxicity studies. This finding was reversible and has also been observed with other substances of this class. Animal studies did not indicate any negative effect on female fertility.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[To be completed nationally]

6.2 Incompatibilities

[To be completed nationally]

6.3 Shelf life

[To be completed nationally]

6.4 Special precautions for storage

[To be completed nationally]

6.5 Nature and contents of container

[To be completed nationally]

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Famvir and associated names (see Annex I) 125 mg film-coated tablets
Famvir and associated names (see Annex I) 250 mg film-coated tablets
Famvir and associated names (see Annex I) 500 mg film-coated tablets
[See Annex I - To be completed nationally]

famciclovir

2. STATEMENT OF ACTIVE SUBSTANCE(S)

[To be completed nationally]

3. LIST OF EXCIPIENTS

[To be completed nationally]

4. PHARMACEUTICAL FORM AND CONTENTS

Film-coated tablets
[To be completed nationally]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

[To be completed nationally]

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

[See Annex I - To be completed nationally]

12. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

[To be completed nationally]

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

[To be completed nationally]

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Famvir and associated names (see Annex I) 125 mg film-coated tablets
Famvir and associated names (see Annex I) 250 mg film-coated tablets
Famvir and associated names (see Annex I) 500 mg film-coated tablets
[See Annex I - To be completed nationally]

famciclovir

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[To be completed nationally]

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Famvir and associated names (see Annex I) 125 mg film-coated tablets
Famvir and associated names (see Annex I) 250 mg film-coated tablets
Famvir and associated names (see Annex I) 500 mg film-coated tablets
[See Annex I - To be completed nationally]

famciclovir

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.
- Famvir 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 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. BEFORE YOU TAKE FAMVIR

Do not take Famvir
- If you are allergic (hypersensitive) to famciclovir, to any of the other ingredients of Famvir 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 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.

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 Famvir with food and drink
You can take Famvir with or without food.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

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

If you are breast-feeding, tell your doctor. 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
In rare cases Famvir can cause dizziness, drowsiness or confusion. **Do not drive or use machines** if you have any of these symptoms while taking Famvir.

Important information about some of the ingredients of Famvir
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 125 mg, 250 mg and 500 mg (country specific) tablets contain lactose.

3. HOW TO TAKE FAMVIR

Always take Famvir 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 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

- 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.

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 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Famvir can cause side effects, although not everybody gets them. The side effects caused by Famvir 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 Famvir 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 FAMVIR

- Keep out of the reach and sight of children.
- Do not use Famvir after the expiry date which is stated on the label after the expiry date. The expiry date refers to the last day of that month.
- [To be completed nationally]
- Do not use Famvir 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 Famvir contains

[To be completed nationally]

What Famvir looks like and contents of the pack

Film–coated tablets
[To be completed nationally]

Marketing Authorisation Holder and Manufacturer

[See Annex I - To be completed nationally]
{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

This medicinal product is authorised in the Member States of the EEA under the following names:

[See Annex I - To be completed nationally]

This leaflet was last approved in {MM/YYYY}.

[To be completed nationally]