Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

Decentralised Procedures

Famciclovir 125mg film-coated tablets
Famciclovir 250mg film-coated tablets
Famciclovir 500mg film-coated tablets

(famciclovir)

Procedure Nos: UK/H/1150/001-3/DC

UK Licence No: PL 30306/0537-0539

Actavis Group PTC ehf

Lay Summary

Famciclovir 125mg film-coated tablets
Famciclovir 250mg film-coated tablets
Famciclovir 500mg film-coated tablets
(famciclovir)

This is a summary of the Public Assessment Report (PAR) for Famciclovir 125 mg, 250 mg and 500 mg Film-coated Tablets (PL 30306/0537-0539; UK/H/1150/001-3/DC). Famciclovir 125 mg, 250 mg and 500 mg Film-coated Tablets will be referred to as Famciclovir Tablets throughout this report, for ease of reading. It explains how Famciclovir Tablets were assessed and their authorisation recommended, as well as the conditions of use. It is not intended to provide practical advice on how to use Famciclovir Tablets.

For practical information about using Famciclovir Tablets, patients should read the package leaflets or contact their doctor or pharmacist.

What are Famciclovir Tablets and what are they used for?
Famciclovir Tablets are 'generic medicines'. This means that they are similar to 'reference medicines', already authorised in the European Union (EU) Famvir 125 mg, 250 mg and 500 mg Tablets (Novartis Pharmaceuticals UK Limited; PL 00101/0623-25).

Famciclovir 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). 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.

How do Famciclovir Tablets work?
Famciclovir Tablets contain the active substance famciclovir which is an antiviral medicine. It stops the infecting virus from reproducing.

How are Famciclovir Tablets used?
Famciclovir Tablets are taken orally.

The daily dose and length of treatment will depend on the type of viral infection.

Dose for shingles
The recommended dose in patients with a normal immune system is one tablet of 500 mg, three times a day, for seven days.
The recommended dose in patients with a reduced immune system is one tablet of 500 mg three times a day, for ten days.

Dose for genital herpes
The dose depends on the state of patient's immune system, and the stage of their infection.

Patients with 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.

Patients with 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.

Famciclovir Tablets can only be obtained with a prescription from a doctor.

For further information on how Famciclovir Tablets are used, please see the Summaries of Product Characteristics or the package leaflet available on the MHRA website.

How have Famciclovir Tablets been studied?
Because Famciclovir Tablets are generic medicines, studies in patients have been limited to tests to determine that they are bioequivalent to the reference medicines, Famvir 125 mg, 250 mg and 500 mg Tablets. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Famciclovir Tablets?
Because Famciclovir Tablets are generic medicines and are bioequivalent to the reference medicines, their benefits and risks are taken as being the same as the reference medicines**.**

Why are Famciclovir Tablets approved?
It was concluded that, in accordance with EU requirements, Famciclovir Tablets have been shown to have comparable quality and be bioequivalent to Famvir 125 mg, 250 mg and 500 mg Tablets. Therefore, the view was that, as for Famvir 125 mg, 250 mg and 500 mg Tablets, the benefits outweigh the identified risks.

What measures are being taken to ensure the safe and effective use of Famciclovir Tablets?
A satisfactory pharmacovigilance system has been provided to monitor the safety of these products.

Other information about Famciclovir Tablets
Marketing Authorisations for Famciclovir 125 mg, 250 mg, 500 mg and 750 mg Film-coated Tablets (PL 18909/0225-8) were granted in the UK to Arrow Generics Limited on 14 October 2008. The Marketing Authorisation for Famciclovir 750 mg Film-coated Tablets was cancelled on 17 December 2010 (PL 18909/0228).

Changes of ownership were granted for the remaining strengths (125mg, 250mg & 500mg) on 07 February 2014, to change the Marketing Authorisation Holder to Actavis Group PTC EHF (PL 30306/0537-39).

The full PAR for Famciclovir Tablets follows this summary.

For more information about treatment with Famciclovir Tablets, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in June 2016.

Table of Contents

I Introduction

Based on the review of the data on quality, safety and efficacy, the Reference Member State (RMS) and Concerned Member States (CMSs) considered that the applications for the medicinal products Famciclovir 125 mg, 250 mg, 500 mg and 750 mg film-coated tablets (PL 18909/0225-0228, UK/H/1150/001-04/DC) are approvable.

The products are prescription-only medicines.

These are abridged applications for Famciclovir 125mg, 250mg, 500mg and 750mg film-coated tablets; four strengths of famciclovir, submitted under Article 10.1 of 2001/83 EC, as amended. The applications refer to the innovator products, Famvir 125mg, 250mg, 500mg and 750mg tablets (PL 00101/0625, 0624, 0623 & 0622 respectively), authorised to Novartis Pharmaceuticals UK Limited in 2001 as Change of Ownerships from the original SmithKline Beecham plc licences that were granted in August 1996. The reference products have been authorised in the UK for more than 10 years, so the period of data exclusivity has expired.

Famciclovir is the pro-drug 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. 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.

Famciclovir has been licensed for the following indications:

- 125mg, 250mg and 500mg tablets - for the treatment of *herpes zoster* (shingles) infections, acute first episode and recurrent genital herpes infections; for the suppression of recurrent genital herpes infections; and for the treatment of *herpes zoster* and *herpes simplex* infections in immunocompromised patients.
- 750 mg tablets for the treatment of *herpes zoster* (shingles) infections.

The adult dose for first-episode genital herpes infections is 250mg three times daily for five days; for the acute treatment of recurrent genital herpes infections is 125mg twice daily for five days. For *herpes zoster* (shingles), the adult dose is 250mg three times daily for seven days or 750mg once daily for seven days. In immunocompromised patients, the acute treatment dose for recurrent genital herpes infections is 500mg twice daily for seven days; and the dose for shingles is 500mg three times daily for 10 days. Famciclovir is not recommended for use in children and adolescents below 18 years of age.

No new non-clinical or clinical studies were conducted, which is acceptable given that the applications were for generic versions of products that have been licensed for over 10 years.

The applications are supported by the single bioequivalence study presented by the applicant comparing the test product, Famciclovir 750 mg film-coated tablets, to the reference product Famvir 750 mg tablets (Novartis Pharmaceuticals UK Limited). The bioequivalence study was carried out in accordance with Good Clinical Practice (GCP).

The Reference Member State (RMS) has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these product types at all sites responsible for the manufacture and assembly of this product. Evidence of compliance with GMP has been provided for the named manufacturing and assembly sites.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the Community, the RMS has accepted copies of current GMP Certificates of satisfactory inspection summary reports, 'close-out letters' or 'exchange of information' issued by the inspection services of the competent authorities (or those countries with which the EEA has a Mutual Recognition Agreement for their own territories) as certification that acceptable standards of GMP are in place at those non-Community sites.

The Marketing Authorisation for Famciclovir 750 mg film-coated tablets was cancelled on 17 December 2010 (PL 18909/0228).

Changes of ownership were granted for the remaining strengths (125mg, 250mg & 500mg) on 07 February 2014, to change the Marketing Authorisation Holder to Actavis Group PTC EHF (PL 30306/0537-39).

II Quality aspects

II.1 Introduction

The drug products are presented as white, round or capsule shaped, film-coated tablets, each tablet containing 125mg, 250mg, 500mg or 750mg of the active ingredient famciclovir.

Other ingredients consist of pharmaceutical excipients, namely sodium starch glycolate (Type A), microcrystalline cellulose, magnesium stearate, and hydroxypropylcellulose making up the tablet cores; and Opadry II 85F18378 White making up the tablet coatings. Opadry II 85F18378 White has four constituents - titanium dioxide (E171), polyvinyl alcohol, macrogol 3350 and talc. Appropriate justification for the inclusion of all tablet excipients has been provided.

All excipients used comply with their respective European Pharmacopoeia monographs, with the exception of Opadry II 85F18378 White which complies with satisfactory in-house specifications. Satisfactory Certificates of Analysis have been provided for all excipients.

No excipients of human or animal origin are used in the formulation or manufacture of Famciclovir tablets. A declaration from the manufacturer of magnesium stearate is provided stating that only material of vegetable origin is used.

There were no novel excipients used and no overages.

The bulk tablets are stored in clear polyethylene (LDPE) bags contained in polypropylene containers with polyethylene snap-on closures. The bulk tablets are in contact with the polyethylene bag only and confirmation has been provided that these polyethylene bags conform to Directive 2002/72/EC.

The finished products are licensed for marketing in polyvinylchloride (PVC) / polyvinylidene chloride (PVdC) / aluminium foil blister strips, which are placed with the Patient Information Leaflet (PIL) into cardboard outer cartons. The licensed pack sizes for the different tablet strengths may be found by referring to the SPCs / patient information leaflets. The MA Holder has stated that not all pack sizes may be marketed.

Specifications and Certificates of Analysis for all packaging components used have been provided. These are satisfactory. All primary product packaging complies with EU legislation, Directive 2002/72/EC (as amended), and is suitable for contact with foodstuffs.

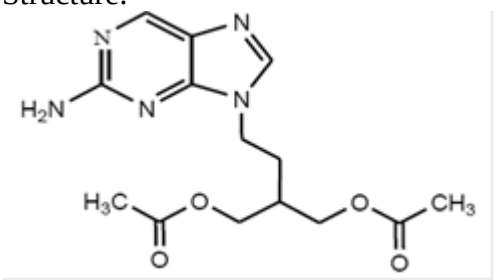
II.2 Drug Substance

Famciclovir

INN: Famciclovir

Chemical Name: 2-[2-(2-Amino-9 H -purin-9-yl) ethyl]-1,3-propanediol diacetate

Structure:



Molecular formula:	$C_{14}H_{19}N_5O_4$
Molecular weight:	321.34 g/mol
CAS No:	104227-87-4
Physical form:	White to off-white crystalline powder.
Solubility:	Freely soluble in water, methanol, ethanol and chloroform, slightly soluble in ethyl acetate and practically insoluble in ether.

The active substance, famciclovir, is not the subject of a European Pharmacopeia (EP) monograph.

Synthesis of the drug substance from the designated starting material has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specifications are in place for all starting materials and reagents and these are supported by relevant Certificates of Analysis. Confirmation has been provided that the raw materials, intermediates and auxiliary agents used in synthesis of the active are not of animal or biological origin, and therefore comply with the TSE requirements.

An appropriate specification has been provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications. Batch analysis data are provided and comply with the proposed specification. Satisfactory Certificates of Analysis have been provided for any reference standards used by the active substance manufacturer during validation studies.

The active substance is stored in appropriate packaging. Specifications and Certificates of Analysis have been provided for the packaging materials used. The primary packaging in direct contact with the active substance satisfies Directive 2002/72/EC (as amended), and is suitable for contact with foodstuffs.

Appropriate stability data have been generated for the active substance stored in the proposed commercial packaging. These data demonstrate the stability of the active substance and a suitable retest period has been set.

II.3 Medicinal Product

Pharmaceutical development

Details of the pharmaceutical development of the drug products have been supplied and are satisfactory.

Comparative dissolution profiles were provided for each tablet strength for the applicants Famciclovir tablets and their respective UK reference products (Famvir tablets). The dissolution profiles were found to be similar.

Manufacture of the products

A description and flow-chart of the manufacturing method has been provided.

In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation studies have been conducted and are satisfactory.

Product Specifications

The finished product specifications are provided for both release and shelf life and are satisfactory; they provide an assurance of the quality and consistency of the finished products. The specifications are in line with ICH Q6A and Ph Eur requirements for tablets. Acceptance limits have been justified with respect to conventional pharmaceutical

requirements and, where appropriate, safety. The test methods have been described and have been adequately validated, as appropriate. Batch data have been provided that comply with the release specifications. Certificates of Analysis have been provided for any reference standards used.

Stability of the products
Finished product stability studies have been conducted in accordance with current guidelines and results were within the proposed specification limits. Based on the results, a shelf-life of 30 months has been set, which is satisfactory. Storage conditions are 'Store in the original package'.

Bioequivalence Study
A bioequivalence study was presented comparing the test product, Famciclovir 750 mg film-coated tablets, to the reference product, Famvir 750 mg tablets (Novartis Pharmaceuticals UK Limited).

An evaluation of the bioequivalence study is found in the Clinical Aspects section.

II.4 Discussion on chemical, pharmaceutical and biological aspects
The test products are pharmaceutically equivalent to the reference products which have been licensed in the UK for over 10 years. The drug products correspond to the current EU definition of a generic medicinal product because they comply with the criteria of having the same qualitative and quantitative composition in terms of the active substance and are the same pharmaceutical form. On this basis, and considering the bioequivalence data provided, the applicant's claim that Famciclovir 750mg film-coated tablets is a generic medicinal product of Famvir 750mg tablets (Novartis Pharmaceuticals UK Limited) is justified. The results and conclusions of the bioequivalence study on the 750 mg strength tablets were extrapolated to the 125 mg, 250 mg and 500 mg strength tablets.

The grant of Marketing Authorisations is recommended.

III Non-clinical aspects
Specific non-clinical studies have not been performed, which is acceptable for these applications for generic versions of a product that has been licensed for over 10 years. The non-clinical overview provides a satisfactory review of the pharmacological, pharmacokinetic and toxicological properties of famciclovir, which is a widely used and well-known active substance.

IV Clinical aspects
IV.1 Introduction
The clinical pharmacology of famciclovir is well known. No novel pharmacodynamic data are supplied or required for this application.

IV.2 Pharmacokinetics
The applicant has conducted a single bioequivalence study comparing the pharmacokinetic profiles of Famciclovir 750 mg film-coated tablets (test) and Famvir 750 mg tablets, Novartis Pharmaceuticals UK Limited (reference). The study was of an appropriate design and was conducted to principles of good clinical practice. This was an open-label, randomised, two-treatment, two-period, two sequence, single dose crossover bioavailability and bioequivalence study conducted in healthy adult human subjects under fasting conditions.

A single dose of the investigational products was administered orally to each subject in each period, following an overnight fast. A satisfactory washout period of 7 days was maintained between the two dosing days in each group. This was sufficient to allow the complete elimination of the drugs and so avoid carry-over effects.

Blood samples were collected over 12 hours post-dose, which was sufficient to adequately characterise the concentration time profiles. The plasma samples were assayed for penciclovir using a validated liquid chromatographic tandem mass spectrometric analytical method

Bioequivalence of the test product versus the reference product was concluded if the 90% Confidence Intervals fell within the acceptance range of 0.8-1.25 for C_{max}, AUC_{0-t}, and $AUC_{0-\infty}$.

Results:

Thirty adverse events were reported, all were mild in nature, with headache and dizziness as the most common events. These are known effects, already detailed in the SmPCs. No new safety issues were identified. The summary of the results of the bioequivalence study are tabulated below.

Pharmacokinetic results for a randomised single dose 2-way crossover study between the test and reference products. Healthy subjects, dosed fasted; t=12 hours. Wash-out period: 7 days

Analyte: Penciclovir					
Parameter	**Geometric Means Arithmetic Means (CV%)**		**Ratio of Geometric Means (%)**	**90% Confidence Interval (%)**	**Intra-Subject (CV%)**
	Treatment A (Test)	**Treatment B (Reference)**			
AUCt (ng*h/mL)	16547.1 16862.2 (21)	16491.1 16743.8 (19)	100.34	97.85-102.89	5
AUCinf (ng*h/mL)	16865.1 17197.3 (21)	16801.6 17069.3 (19)	100.38	97.91-102.91	5
C_{max} (ng/mL)	5608.8 5787.8 (26)	5656.2 5797.8 (23)	99.16	93.07-105.65	14

The statistical results indicated that the 90% confidence intervals of the test/reference geometric mean ratios for: AUC_t, AUC_{inf}, and C_{max} of penciclovir were within the 80.00% to 125.00% range, in line with the CPMP guidance CHMP/EWP/QWP/1401/98 ((Note for Guidance on the Investigation of Bioavailability and Bioequivalence). Therefore, Famciclovir 750 mg film-coated tablets (Arrow Generics Limited, UK) is shown to be bioequivalent to Famvir 750 mg Tablets (Novartis Pharmaceuticals UK Limited, England).

Conclusion on Bioequivalence

The results of the bioequivalence study show that the test product and reference product are bioequivalent as the confidence intervals for C_{max}, AUC_{0-t}, and $AUC_{0-\infty}$ fall within the acceptance criteria ranges of 80-125% in line with current guidelines.

Satisfactory justification is provided for a bio-waiver for Famciclovir 125mg, 250mg and 500mg film-coated tablets. As Famciclovir 125mg, 250mg, 500mg and 750mg film-coated tablets meet the criteria specified in the Note for Guidance on the investigation of

bioavailability and bioequivalence, the results and conclusions of the bioequivalence study on the 750mg strength were extrapolated to the 125mg, 250mg and 500mg strength products.

IV.3 Pharmacodynamics
No new pharmacodynamics data are required for these applications and none have been submitted.

IV.4 Clinical efficacy
No new data have been submitted and none are required. Efficacy is reviewed in the clinical overview. The efficacy of famciclovir is well-established from its extensive use in clinical practice.

IV.5 Clinical safety
No new data have been submitted and none are required for applications of this type. Safety is reviewed in the clinical overview. The safety profile of famciclovir is well-known.

IV.6 Pharmacovigilance System
A satisfactory pharmacovigilance system has been provided to monitor the safety of this product.

IV.7 Discussion on the clinical aspects
The grant of marketing authorisations is recommended for these applications.

V User consultation
Package leaflets have been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflets are well-structured and organised, easy to understand and written in a comprehensive manner. The tests show that the patients/users are able to act upon the information that the leaflets contain.

VI Overall conclusion, benefit/risk assessment and recommendation
QUALITY

The important quality characteristics of Famciclovir 125mg, 250mg, 500mg and 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.

NON-CLINICAL

No new non-clinical data were submitted and none are required for applications of this type.

CLINICAL

Bioequivalence has been demonstrated between the applicant’s Famciclovir 750mg film-coated tablets, and the reference product, Famvir 750mg tablets (PL 00101/0622, Novartis Pharmaceuticals UK Limited).

As Famciclovir 125mg, 250mg, 500mg and 750mg film-coated tablets were deemed to meet the criteria specified in the Note for Guidance on the investigation of bioavailability and bioequivalence (CPMP/EWP/QWP/1401/98), the results and conclusions of the bioequivalence study on the 750mg strength were extrapolated to the 125mg, 250mg and 500mg strength products, and no separate bioequivalence studies were necessary.

No new or unexpected safety concerns arose from these applications.

The quality of the products is acceptable and no new non-clinical or clinical concerns have been identified. The bioequivalence study and the valid extrapolation of its results and conclusions support the claim that the applicant's products and their respective reference products are interchangeable. Extensive clinical experience with famciclovir is considered to have demonstrated the therapeutic value of the active substance. The risk benefit is, therefore, considered to be positive.

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory, in line with current guidelines and consistent with the reference products. In accordance with Directive 2012/84/EU, the current approved UK versions of the SmPCs and PILs for these products are available on the MHRA website. The current approved UK labelling is available in Annex 1.

Table of content of the PAR update for MRP and DCP

Steps taken after the initial procedure with an influence on the Public Assessment Report

(Type II variations, PSURs, commitments)

The following table lists a non-safety update to the Marketing Authorisations for these products that has been approved by the MHRA since the products were first licensed. The table includes updates that are detailed in the annex to this PAR. This is not a complete list of the post-authorisation changes that have been made to these Marketing Authorisations.

Scope	**Procedure numbers**	**Product information affected**	**Date of start of the procedures**	**Date of end of procedures**	**Approval / non approval**	**Assessment report attached Y/N (version)**
To update sections 2 (Qualitative and quantitative composition), 4.2 (Posology and method of administration), 4.3 (Contraindications), 4.6 (Fertility, pregnancy and lactation), 4.8 (Undesirable effects), 5.1 (Pharmacodynamic properties) and 5.2 (Pharmacokinetic properties) of the SmPC, label and the leaflet in line with the Quality Review of Documents (QRD) template.	UK/H/1150/001-3/1B/010	SmPC, PIL and Labelling	15/06/2015	20/05/2016	Approved	Yes

Annex 1

Reference: **PL 30306/0537-0006; PL 30306/0538-0006; PL 30306/0539-0006**

European Procedure Number: UK/H/1150/001-3/1B/010

Product: **Famciclovir 125 mg, 250 mg and 500 mg Film-coated Tablets**

Marketing Authorisation Holder: Actavis Group PTC ehf

Active Ingredient: **Famciclovir**

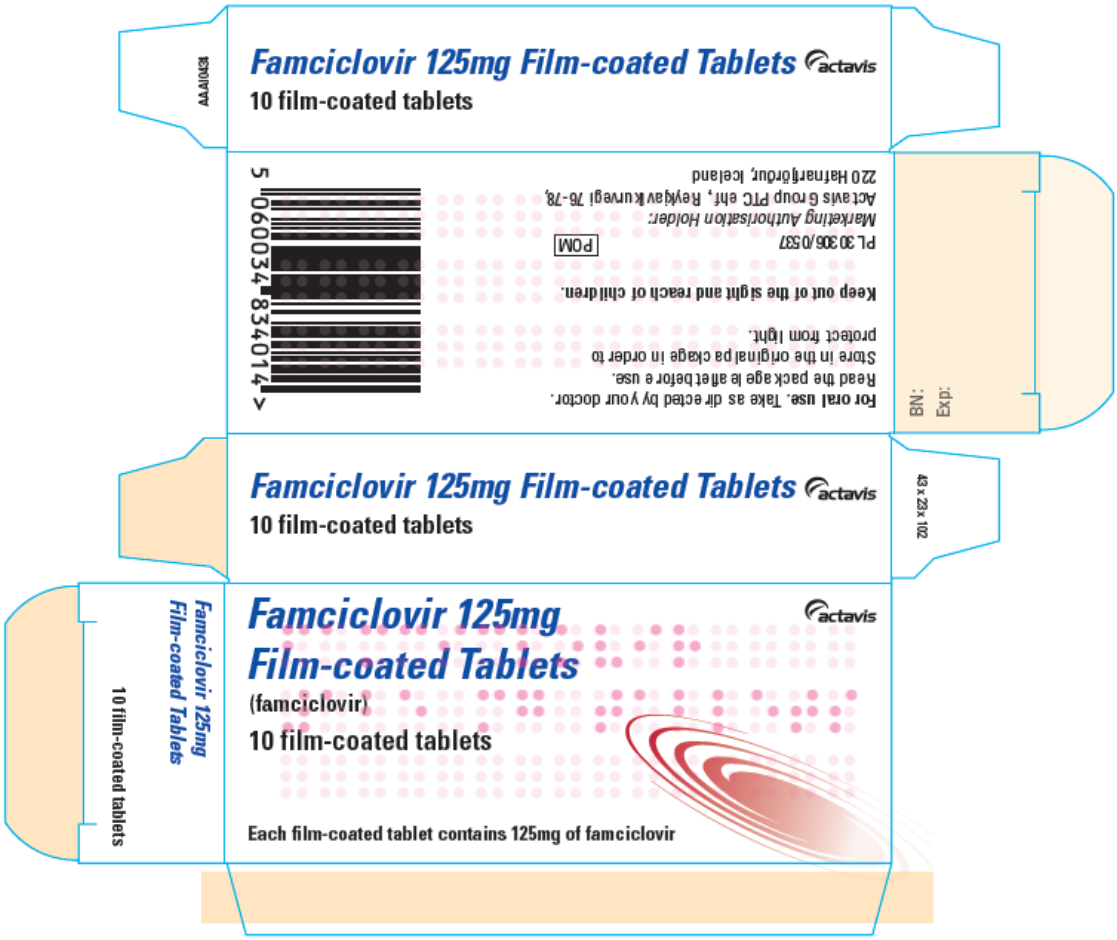
Reason:
To update sections 2 (Qualitative and quantitative composition), 4.2 (Posology and method of administration), 4.3 (Contraindications), 4.6 (Fertility, pregnancy and lactation), 4.8 (Undesirable effects), 5.1 (Pharmacodynamic properties) and 5.2 (Pharmacokinetic properties) of the SmPC, label and the leaflet in line with the Quality Review of Documents (QRD) template.

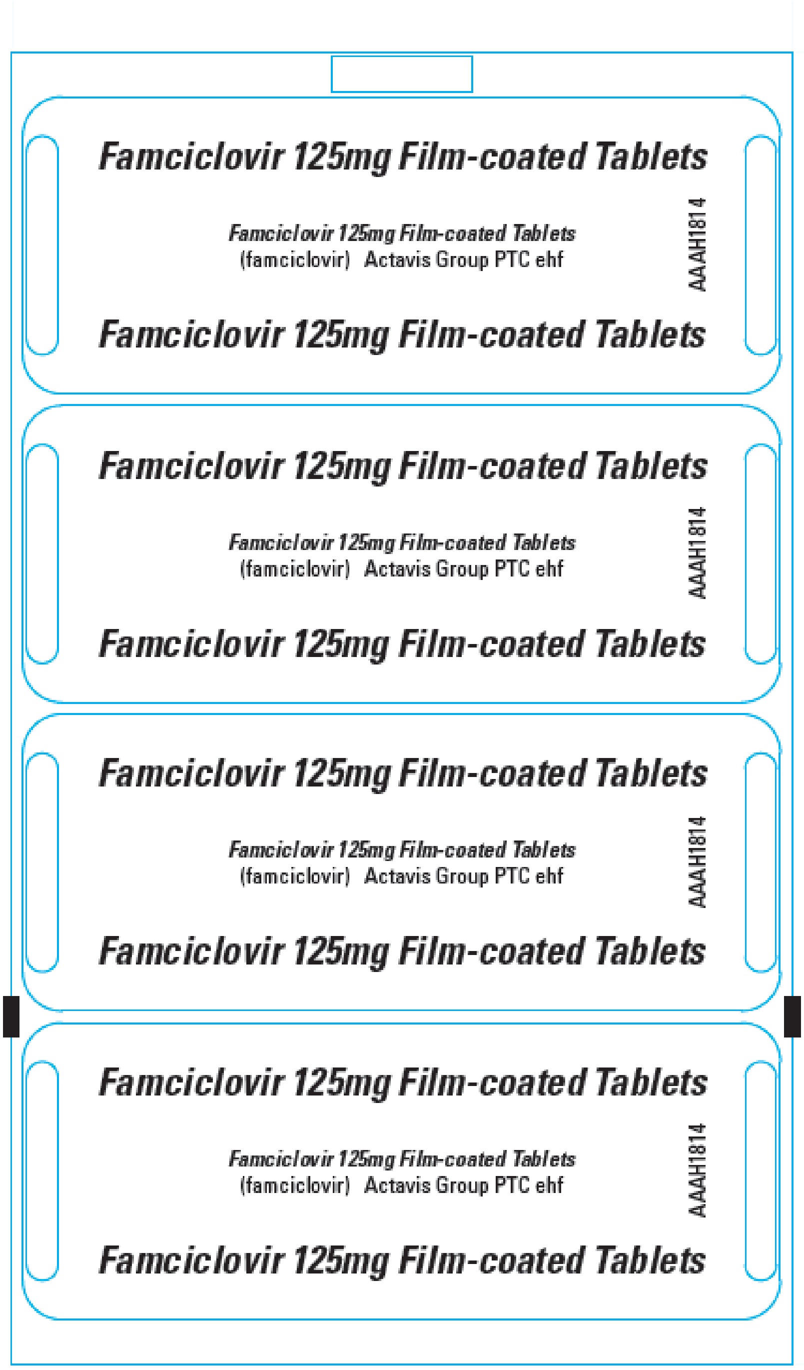
Supporting evidence
The applicant has submitted updated sections of the SmPCs, PIL and labelling.

Evaluation
The amended sections of the SmPCs, PIL and labelling are satisfactory.

Conclusion
The variation procedures were approved on 20 May 2016 and the updated SmPC fragments, PIL and labelling were incorporated into each Marketing Authorisation.

The current approved UK labelling is presented below.


Famciclovir 125mg Film-coated Tablets
actavis
10 film-coated tablets
5 060034 834014
For oral use. Take as directed by your doctor.
Read the package leaflet before use.
Store in the original package in order to protect from light.
Keep out of the sight and reach of children.
POM
PL 30306/0537
Marketing Authorisation Holder:
Actavis Group PTC ehf., Reykjavikurvegi 76-78,
220 Hafnarfjörður, Iceland
BN:
Exp:
43 x 23 x 102
Famciclovir 125mg Film-coated Tablets
actavis
10 film-coated tablets
Famciclovir 125mg Film-coated Tablets
10 film-coated tablets
Famciclovir 125mg Film-coated Tablets
actavis
(famciclovir)
10 film-coated tablets
Each film-coated tablet contains 125mg of famciclovir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(famciclovir) Actavis Group PTC ehf
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Famciclovir 125mg Film-coated Tablets


AAA10495
Famciclovir 250mg Film-coated Tablets
21 film-coated tablets
actavis
5 060034 834038 >
PL 30306/0538
Marketing Authorisation Holder:
Actavis Group PTC ehf., Reykjavikurvegi 76-78,
220 Hafnarfjörður, Iceland
POM
Keep out of the sight and reach of children.
For oral use. Take as directed by your doctor.
Read the package leaflet before use.
Store in the original package in order to
protect from light.
BN:
EXP:
Famciclovir 250mg Film-coated Tablets
21 film-coated tablets
actavis
53 x 23 x 130
Famciclovir 250mg Film-coated Tablets
21 film-coated tablets
Famciclovir 250mg
Film-coated Tablets
(famciclovir)
21 film-coated tablets
Each film-coated tablet contains 250mg of famciclovir


Famciclovir 250mg Film-coated Tablets
Famciclovir 250mg Film-coated Tablets (famciclovir) Actavis Group PTC ehf
Famciclovir 250mg Film-coated Tablets
Famciclovir 250mg Film-coated Tablets (famciclovir) Actavis Group PTC ehf
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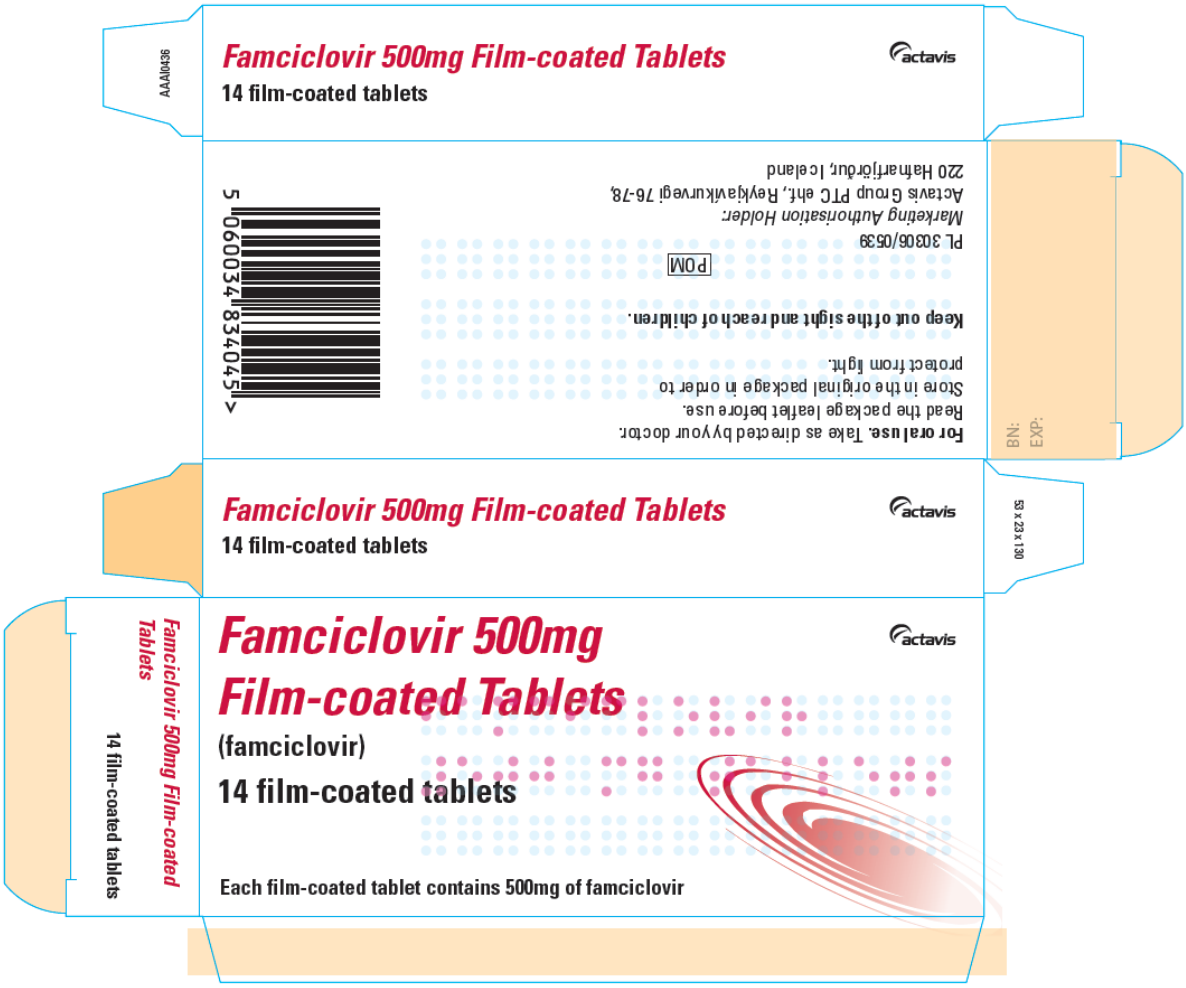
AAAH1816


Famciclovir 500mg Film-coated Tablets
14 film-coated tablets
actavis
AA0106
5 060034 834045
For oral use. Take as directed by your doctor.
Read the package leaflet before use.
Store in the original package in order to protect from light.
Keep out of the sight and reach of children.
POM
PL 30306/0539
Marketing Authorisation Holder:
Actavis Group PTC ehf., Reykjavikurvegi 76-78,
220 Hafnarfjörður, Iceland
BN:
EXP:
53 x 23 x 130
Famciclovir 500mg Film-coated Tablets
14 film-coated tablets
actavis
Famciclovir 500mg Film-coated Tablets
(famciclovir)
14 film-coated tablets
Each film-coated tablet contains 500mg of famciclovir
Famciclovir 500mg Film-coated Tablets
14 film-coated tablets

Decision : Grant
Date: 20 May 2016