Public Assessment Report

Scientific discussion

Abacavir/Lamivudine/Zidovudine Mylan 300 mg/ 150 mg/300 mg, film-coated tablets

(abacavir/lamivudine/zidovudine)

NL/H/2864/001/DC

Date: 29 July 2014

This module reflects the scientific discussion for the approval of Abacavir/ Lamivudine/Zidovudine Mylan 300 mg/150 mg/300 mg, film-coated tablets. The procedure was finalised on 1 April 2014. For information on changes after this date please refer to the module 'Update'.

This report includes a summary, on pages 11-13.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have granted a marketing authorisation for Abacavir/Lamivudine/Zidovudine Mylan 300 mg/150 mg/300 mg, film-coated tablets from Mylan B.V.

The fixed combination of abacavir/lamivudine/zidovudine is indicated for the treatment of Human Immunodeficiency Virus (HIV) infection in adults. It replaces the three components (abacavir, lamivudine and zidovudine) used separately in similar doses. It is recommended that treatment is started with abacavir, lamivudine, and zidovudine separately for the first 6-8 weeks. The choice of this fixed combination should be based not only on potential adherence criteria, but mainly on expected efficacy and risk related to the three nucleoside analogues.

The demonstration of the benefit of abacavir/lamivudine/zidovudine is mainly based on results of studies performed in treatment-naïve patients or moderately antiretroviral-experienced patients with non- advanced disease. In patients with high viral load (> 100,000 copies/ml) choice of therapy needs special consideration.

Before initiating treatment with abacavir, screening for carriage of the HLA-B*5701 allele should be performed in any HIV-infected patient, irrespective of racial origin. Screening is also recommended prior to re-initiation of abacavir in patients of unknown HLA-B*5701 status who have previously tolerated abacavir. Abacavir should not be used in patients known to carry the HLA-B*5701 allele, unless no other therapeutic option is available in these patients, based on the treatment history and resistance testing. Studies have shown that carriage of the HLA-B*5701 allele is associated with a significantly increased risk of a hypersensitivity reaction to abacavir.

A comprehensive description of the indications and posology is given in the SmPC.

This decentralised procedure concerns a generic application claiming essential similarity with the innovator product Trizivir 300/150/300 mg film-coated tablets, which has been registered in the EEA by ViiV Healthcare UK Limited since 28 December 2000 (original product). The product was authorised through centralised procedure EMEA/H/C/000338. The individual active substances were registered as single component formulations in 1987 (zidovudine; national registration in the Netherlands), 1996 (lamivudine; centralised procedure) and 1999 (abacavir; centralised procedure).

The concerned member states (CMS) involved in this procedure were Belgium, France, Germany, Italy, Luxembourg, Spain and the United Kingdom.

The marketing authorisation has been granted pursuant to Article 10(1) of Directive 2001/83/EC.

II. QUALITY ASPECTS

II.1 Introduction

Abacavir/Lamivudine/Zidovudine Mylan 300 mg/150 mg/300 mg is a light green, oval shaped, biconvex, film-coated tablet debossed with ‘ALZ1’ on one side and ‘M’ on other side.

The film-coated tablets are packed in PVC-ACLAR/Al blisters, Al/Al blister or in white HDPE bottles with PP closure.

The excipients are:
Tablet core – microcrystalline cellulose (PH 102), colloidal anhydrous silica, sodium starch glycolate (Type A), magnesium stearate.
Film-coating – Opadry Green 03B510004, containing hypromellose 6cP, titanium dioxide (E171), macrogol 400, indigo carmine aluminium lake (E132), iron oxide yellow (E172), iron oxide red (E172)

II.2 Drug Substances

Abacavir sulfate

The active substance abacavir sulfate is an established active substance described in the European Pharmacopoeia (Ph.Eur.). The active substance is a white or almost white powder, which is slightly soluble in water. Abacavir sulfate has two chiral centers and is manufactured as an enantiomer with 1S,4R configuration. Abacavir sulfate is non-hygroscopic and does not exhibit polymorphism.

The Active Substance Master File (ASMF) procedure is used for abacavir sulfate. The main objective of the ASMF procedure, commonly known as the European Drug Master File (EDMF) procedure, is to allow valuable confidential intellectual property or 'know-how' of the manufacturer of the active substance (ASM) to be protected, while at the same time allowing the applicant or marketing authorisation holder (MAH) to take full responsibility for the medicinal product, the quality and quality control of the active substance. Competent Authorities/EMA thus have access to the complete information that is necessary to evaluate the suitability of the use of the active substance in the medicinal product.

Manufacturing process
The manufacturing process consists of four steps: two synthetic step and two salt formation steps. No class 1 organic solvents or heavy metal catalysts are used. The proposed starting materials are acceptable. Acceptable specifications have been adopted for the solvents and reagents. The active substance has been adequately characterised.

Quality control of drug substance
The drug substance specification is base don the Ph.Eur. monograph, with additional requirements for residual solvents. The specification is acceptable in view of the route of synthesis and the various European guidelines. Batch analytical data demonstrating compliance with the drug substance specification have been provided for three full-scale batches.

Stability of drug substance
Stability data on the active substance have been provided for six full-scale batches stored at 25°C/60% RH (60 months) and 40°C/75% RH (6 months). All parameters tested remain relatively stable at both storage conditions.
Based on the stability data provided the proposed re-test period of 5 years was granted with the applicable storage conditions: 'Store in air-tight container, protect from light, below 30°C'.

Lamivudine
The second active substance is lamivudine, an established active substance described in the European Pharmacopoeia.. The active substance is a white or almost white powder, which is soluble in water. The active substance shows polymorphism and is optically active.

The CEP procedure is used for lamivudine. Under the official Certification Procedures of the EDQM of the Council of Europe, manufacturers or suppliers of substances for pharmaceutical use can apply for a certificate of suitability concerning the control of the chemical purity and microbiological quality of their substance according to the corresponding specific monograph, or the evaluation of reduction of Transmissible Spongiform Encephalopathy (TSE) risk, according to the general monograph, or both. This procedure is meant to ensure that the quality of substances is guaranteed and that these substances comply with the European Pharmacopoeia.

Manufacturing process
A CEP has been submitted; therefore no details on the manufacturing process have been included.

Quality control of drug substance
The drug substance specification is in line with the CEP, with some additional requirements. The specification is acceptable in view of the route of synthesis and the various European guidelines. Batch analytical data demonstrating compliance with the drug substance specification have been provided for two full-scale batches.

Stability of drug substance
The active substance is stable for 2 years when stored under the stated conditions. Assessment thereof was part of granting the CEP and has been granted by the EDQM.

Zidovudine
The active substance zidovudine is an established active substance described in the European Pharmacopoeia. The active substance is a white or brownish powder, which is sparingly soluble in water. The active substance shows polymorphism and is optically active.

The CEP procedure is used for this substance.

Manufacturing process
As a CEP has been submitted, no details on the manufacturing process have been included.

Quality control of drug substance
The drug substance specification is in line with the CEP, with some additional requirements. The specification is acceptable in view of the route of synthesis and the various European guidelines.
Batch analytical data demonstrating compliance with the drug substance specification have been provided for three full-scale batches.

Stability of drug substance
The active substance is stable for 60 months when stored under the stated conditions. Assessment thereof was part of granting the CEP and has been granted by the EDQM.

II.3 Medicinal Product

Pharmaceutical development
The development of the product has been described, the choice of excipients is justified and their functions explained. The main development studies performed were the physicochemical characterisation of the active substances, compatibility studies, formulation optimization studies and comparative dissolution studies between the batches used in the bioequivalence study. Similarity of dissolution profiles between the test and reference product used in the bioequivalence study was adequately demonstrated at three pH-levels. The test batch used in the bioequivalence study was manufactured according to the finalized composition and manufacturing process. The pharmaceutical development of het product has been adequately performed.

Manufacturing process
The manufacturing process mainly consists of wet granulation, mixing, compression and film-coating. The process has been adequately validated according to relevant European guidelines. Process validation data on the product has been presented for three batches of the smallest commercial scale. The product is manufactured using conventional manufacturing techniques. Process validation for batches of the maximum commercial scale will be performed post authorisation.

Control of excipients
The excipients comply with Ph.Eur. requirements, with the exception of the film-coating. The specifications are acceptable.

Quality control of drug product
The product specification includes tests for description, identification, identification of the colorants, dissolution, content uniformity, related substances, assay, loss on drying and microbial quality. The release and shelf life limits are identical with the exception of loss on drying. The specification is acceptable.
The analytical methods have been adequately described and validated. Batch analytical data from the proposed production site have been provided on three batches of the smallest commercial scale, demonstrating compliance with the release specification.

Stability of drug product
Stability data on the product has been provided three full-scale batches stored at 25°C/60% RH (18 months) (PVC-Aclar/Al blister, Al/Al blister, HDPE bottle), at 30°/65% RH (12 months) (PVC-Aclar/Al blister, Al/Al blister) and at 40°C/75% RH (6 months) (PVC-Aclar/Al blister, Al/Al blister, HDPE bottle). The conditions used in the stability studies are according to the ICH stability guideline. The batches were stored in the three proposed marketing packages.
Loss on drying increases in all containers at all conditions, most pronounced at long-term conditions. Increases in related substances were observed at accelerated conditions in all containers. However, in the two types of blister the results for related substances went out of specification. At intermediate conditions the results remained within specification. Photostability studies in line with ICH Q1B demonstrated that the product is not sensitive to light.

Based on the stability data provided the following can be granted:

- PVC-Aclar/Al blister and Al/Al blister: 24 months, Do not store above 30°C.

- HPDE bottle: 24 months, No special storage conditions.

In-use stability data has been provided demonstrating that the product remains stable for 60 days following first opening of the bottle, when stored without special storage conditions.

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies
None of the excipients used in the manufacture of the drug product are of animal or human origin. Magnesium stearate is of vegetable origin. Relevant certificates stating TSE/BSE safety have been provided.

II.4 Discussion on chemical, pharmaceutical and biological aspects

Based on the submitted dossier, the member states consider that Abacavir/Lamivudine/Zidovudine Mylan 300 mg/150 mg/300 mg has a proven chemical-pharmaceutical quality. Sufficient controls have been laid down for the active substances and finished product.

The following post-approval commitments were made:
- The MAH committed to perform process validation studies on the first three production-scale batches.
- The MAH committed to continue the on-going long-term stability studies up to 24 months.

III. NON-CLINICAL ASPECTS

III.1 Ecotoxicity/environmental risk assessment (ERA)

Since Abacavir/Lamivudine/Zidovudine Mylan is intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

III.2 Discussion on the non-clinical aspects

This product is a generic formulation of Trizivir, which is available on the European market. Reference is made tot the preclinical data obtained with the innovator product. A non-clinical overview on the pharmacology, pharmacokinetics and toxicology has been provided, which is based on up-to-date and adequate scientific literature. The overview justifies why there is no need to generate additional non-clinical pharmacology, pharmacokinetics and toxicology data. Therefore, the member states agreed that no further non-clinical studies are required.

IV. CLINICAL ASPECTS

IV.1 Introduction

Abacavir, lamivudine and zidovudine are well-known active substances with established efficacy and tolerability.
A clinical overview has been provided, which is based on scientific literature. The overview justifies why there is no need to generate additional clinical data. Therefore, the member states agreed that no further clinical studies are required.

For this generic application, the MAH has submitted a bioequivalence study, which is discussed below.

IV.2 Pharmacokinetics

The MAH conducted a bioequivalence study in which the pharmacokinetic profile of the test product Abacavir/Lamivudine/Zidovudine Mylan 300 mg/150 mg/300 mg (Mylan B.V., the Netherlands) is compared with the pharmacokinetic profile of the reference product Trizivir 300/150/300 mg tablets (GSK, UK).

The choice of the reference product in the bioequivalence study is justified, as it has been registered through a centralised procedure. The formula and preparation of the bioequivalence batch is identical to the formula proposed for marketing.

Bioequivalence study

Design

A single-dose, randomised, two-period, two-treatment, two-sequence, crossover bioequivalence study was carried out under fasted conditions in 54 (+2 standby) healthy male subjects, aged 19-43 years. Each subject received a single dose (300/150/300 mg) of one of the 2 abacavir/lamivudine/zidovudine formulations. The tablet was orally administered with 240 ml water after an overnight fast. Fasting was continued for 4 hours after dosing. There were 2 dosing periods, separated by a washout period of 7 days.

Blood samples were collected pre-dose and at 0.167, 0.333, 0.5, 0.667, 0.833, 1, 1.25, 1.5, 1.75, 2, 2.5, 3, 4, 5, 6, 8, 10, 12, 16, 24 and 36 hours after administration of the products.

A single dose, crossover study under fasting conditions to assess bioequivalence for abacavir, lamivudine and zidovudine is considered adequate. The product can be taken with or without food, according to the SmPC of the innovator.

Analytical/statistical methods

The analytical method has been adequately validated and is considered acceptable for analysis of the plasma samples. The methods used in this study for the pharmacokinetic calculations and statistical evaluation are considered acceptable.

Results

All 54 subjects completed the study and were included in the pharmacokinetic and statistical analysis.

Table 1. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} (median, range)) of abacavir under fasted conditions.

Treatment N=54	**AUC_{0-t}** ng.h/ml	**$AUC_{0-\infty}$** ng.h/ml	**C_{max}** ng/ml	**t_{max}** h	**$t_{1/2}$** h
Test	8636 ± 2175	8738 ± 2205	3472 ± 1214	0.83 (0.33 – 2.50)	1.65 ± 0.60
Reference	8182 ± 2079	8277 ± 2105	3187 ± 1005	1.00 (0.33 – 2.50)	1.53 ± 0.36
***Ratio (90% CI)**	1.06 (1.03 – 1.09)	1.06 (1.03 - 1.09)	1.08 (1.02 - 1.14)	--	--
CV (%)	9.0	9.0	17.1	--	--

$AUC_{0-\infty}$ area under the plasma concentration-time curve from time zero to infinity
AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
C_{max} maximum plasma concentration
t_{max} time for maximum concentration
$t_{1/2}$ half-life

**ln-transformed values*

Table 2. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} (median, range)) of lamivudine under fasted conditions.

Treatment N=54	**AUC_{0-t}** ng.h/ml	**$AUC_{0-\infty}$** ng.h/ml	**C_{max}** ng/ml	**t_{max}** h	**$t_{1/2}$** h
Test	8878 ± 2351	9171 ± 2337	1753 ± 478	1.75 (0.67 – 4.0)	4.78 ± 1.53
Reference	9377 ± 2156	9656 ± 2138	1818 ± 479	1.51 (0.83 – 5.0)	4.75 ± 1.19
***Ratio (90% CI)**	0.94 (0.89 – 0.98)	0.94 (0.90 – 0.98)	0.96 (0.90 - 1.02)	--	--

CV (%)	15.0	14.2	18.7	--	--

$AUC_{0-\infty}$ area under the plasma concentration-time curve from time zero to infinity
AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
C_{max} maximum plasma concentration
t_{max} time for maximum concentration
$t_{1/2}$ half-life

**ln-transformed values*

Table 3. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} (median, range)) of zidovudine under fasted conditions.

Treatment N=54	**AUC_{0-t}** ng.h/ml	**$AUC_{0-\infty}$** ng.h/ml	**C_{max}** ng/ml	**t_{max}** h	**$t_{1/2}$** h
Test	4143 ± 1025	4225 ± 1034	2729 ± 1191	0.67 (0.33 – 2.50)	1.58 ± 0.71
Reference	4016 ± 967	4097 ± 973	2647 ± 1075	0.67 (0.33 – 2.50)	1.56 ± 0.43
***Ratio (90% CI)**	1.03 (1.00 – 1.06)	1.03 (1.00 – 1.06)	1.02 (0.94 - 1.10)	--	--
CV (%)	8.7	8.5	23.5	--	--

$AUC_{0-\infty}$ area under the plasma concentration-time curve from time zero to infinity
AUC_{0-t} area under the plasma concentration-time curve from time zero to t hours
C_{max} maximum plasma concentration
t_{max} time for maximum concentration
$t_{1/2}$ half-life

**ln-transformed values*

Conclusion on bioequivalence study
The 90% confidence intervals calculated for AUC_{0-t}, $AUC_{0-\infty}$ and C_{max} are within the bioequivalence acceptance range of 0.80 – 1.25. Based on the submitted bioequivalence study Abacavir/Lamivudine/ Zidovudine Mylan is considered bioequivalent Trizivir 300 mg/150 mg/300 mg tablets.

The MEB has been assured that the bioequivalence study has been conducted in accordance with acceptable standards of Good Clinical Practice (GCP, see Directive 2005/28/EC) and Good Laboratory Practice (GLP, see Directives 2004/9/EC and 2004/10/EC).

IV.3 Risk Management Plan

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to study Abacavir/Lamivudine/Zidovudine Mylan.

Summary of safety concerns for Abacavir/Lamivudine/Zidovudine:	
Important identified risks	• Hypersensitivity reactions, especially in patients who have the HLA-B5701 gene • Renal failure • Hepatotoxicity, especially in patients with previous VHB/VHC infection • Neutropenia and thrombocytopenia
Important potential risks	• Drug rash with eosinophilia and systemic symptoms (DRESS) • Mitochondrial dysfunction in babies of mothers treated with

	Abacavir/Lamivudine/Zidovudine • Lipodystrophy • Immune reactivation syndrome • Osteonecrosis • Myocardial infarction
Important missing information	• No experience in children and elderly patients • No data on drug interactions, especially with NNRTIs (non-nucleoside reverse transcriptase inhibitors) and PIs (protease inhibitors)

Additional risk minimisation measures are proposed to minimise the risk of hypersensitivity reactions, especially in patients who have the HLA-B5701 gene. The proposed risk minimization measures is a patient alert card included in the package, explaining the high risk of severe hypersensitivity reactions (life-threatening lowering of blood pressure or death) to abacavir (or any other medicine containing abacavir (for example Trizivir, Kivexa or Ziagen)), both in patients who use the drug for the first time and in patients that re-start the treatment.
Proposed method of evaluation of the effectiveness of risk minimisation measures is by routine pharmacovigilance activities. Criteria proposed for judging the success of proposed risk minimization measures is evaluation of adverse reaction reports received from various sources.
The member states agree that for the other important identified risks no additional pharmacovigilance activities beyond routine PV are necessary.

IV.4 Discussion on the clinical aspects

For this authorisation, reference is made to the clinical studies and experience with the innovator product Trizivir. No new clinical studies were conducted. The MAH demonstrated through a bioequivalence study that the pharmacokinetic profile of the product is similar to the pharmacokinetic profile of this reference product. Risk management is adequately addressed. This generic medicinal product can be used instead of the reference product.

V. USER CONSULTATION

No user consultation with target patient groups on the package leaflet (PL) has been performed. Regarding readability reference is made to the user test for Lamivudine/Zidovudine Mylan 150/300 mg film-coated tablets, approved in procedure NL/H/2059/001/DC.
In accordance with CMDh guidance document “Consultation With Target Patient Groups - Meeting The Requirements Of Article 59(3) Without The Need For A Full Test - Recommendations For Bridging” (CMDh/100/2007), bridging to this leaflet is justified because:

- The parent and daughter leaflets are of the same “drug class”.
- The parent and daughter leaflet have similar key messages for safe use.
- The parent and daughter leaflets have the same patient population.
- Any additional messages included in the daughter leaflet have been added in the same writing style.

Additional text relating to Abacavir has been written in the same style and has been taken directly from the reference product leaflet (Trizivir 300 mg/150 mg/300 mg film-coated tablets).

In addition a comparison of format, layout and design of the proposed PL for Abacavir/Lamivudine/ Zidovudine Mylan and the user tested Lamivudine/Zidovudine Mylan has been included. The leaflet width, layout, font types and sizes are identical, as per the Mylan house style. The bridging report submitted by the applicant has been found acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Abacavir/Lamivudine/Zidovudine Mylan 300/150/300 mg film-coated tablets has a proven chemical-pharmaceutical quality and is a form of Trizivir 300/150/300 mg. Trizivir is a well-known medicinal product with an established favourable efficacy and safety profile.

Bioequivalence has been shown to be in compliance with the requirements of European guidance documents.

The Board followed the advice of the assessors.

There was no discussion in the CMD(h). Agreement between member states was reached during a written procedure. The member states, on the basis of the data submitted, considered that essential similarity has been demonstrated for Abacavir/Lamivudine/Zidovudine Mylan 300/150/300 mg with the reference product, and have therefore granted a marketing authorisation. The decentralised procedure was finalised with a positive outcome on 1 April 2014.

The MAH committed to register the educational material prior to marketing the product in each member state on a national basis, as required by the appropriate national competent authority.

STEPS TAKEN AFTER THE FINALISATION OF THE INITIAL PROCEDURE - SUMMARY

Scope	Procedure number	Type of modification	Date of start of the procedure	Date of end of the procedure	Approval/ non approval	Assessment report attached

Summary Public Assessment Report

Generics

Abacavir/Lamivudine/Zidovudine Mylan 300 mg/150 mg/300 mg, film-coated tablets

(abacavir, lamivudine and zidovudine)

NL/H/2864/001/DC

Date: 29 July 2014

Summary Public Assessment Report

Generics

Abacavir/Lamivudine/Zidovudine Mylan 300 mg/150 mg/300 mg, film-coated tablets

Active substances: abacavir, lamivudine and zidovudine

This is a summary of the public assessment report (PAR) for Abacavir/Lamivudine/Zidovudine Mylan. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Abacavir/Lamivudine/ Zidovudine Mylan.

For practical information about using this medicine, patients should read the package leaflet or contact their doctor or pharmacist.

What is Abacavir/Lamivudine/Zidovudine Mylan and what is it used for?
Abacavir/Lamivudine/Zidovudine Mylan 300 mg/150 mg/300 mg is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Trizivir 300 mg/150 mg/300 mg, film-coated tablets.

This medicine contains three active ingredients: abacavir, lamivudine and zidovudine. These substances are used to treat HIV infection. This medicine helps to control the condition.

How is this medicine used?
The medicine can only be obtained with a prescription. The recommended dose for adults is one tablet twice a day. Children and adolescents under 18 years of age should not take this medicine.
The tablets should be taken at regular times, leaving approximately 12 hours between each tablet.
The tablet should be swallowed whole, with some water and can be taken with or without food.

How does this medicine work?
The three active ingredients, abacavir, lamivudine and zidovudine, all belong to a group of anti-retroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs). This medicine does not cure HIV infection. It reduces the amount of virus in the body, and keeps it at a low level. This helps the body to increases the CD4 cell count in the blood. CD4 cells are a type of white blood cell which are important in helping the body to fight infection.

How has this medicine been studied?
Because Abacavir/Lamivudine/Zidovudine Mylan is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Trizivir. Two medicines are bioequivalent when they produce the same levels of the active substances in the body.

What are the benefits and risks of this medicine?
Because Abacavir/Lamivudine/Zidovudine Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine, Trizivir.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to Trizivir. Therefore, the view was that, as for the reference medicine, the benefit outweighs the identified risk.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for this medicine, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about this medicine
In the Netherlands, the marketing authorisation for Abacavir/Lamivudine/Zidovudine Mylan 300 mg/150 mg/300 mg, film-coated tablets was granted on 22 May 2014.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Abacavir/Lamivudine/Zidovudine Mylan, read the package leaflet (http://mri.medagencies.org/download/NL_H_2864_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in July 2014.