Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for ABACAVIR/LAMIVUDINE 600 mg/300 mg film-coated tablets

This is a summary of the risk management plan (RMP) for ABACAVIR/LAMIVUDINE 600 mg/300 mg film-coated tablets (hereinafter referred to as Abacavir/lamivudine). The RMP details important risks of Abacavir/lamivudine, how these risks can be minimised, and how more information will be obtained about Abacavir/lamivudine's risks and uncertainties (missing information).

Abacavir/lamivudine's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Abacavir/lamivudine should be used.

Important new concerns or changes to the current ones will be included in updates of Abacavir/lamivudine's RMP.

I. The Medicine and What It is used for

Abacavir/lamivudine is authorised for antiretroviral combination therapy for the treatment of HIV infection in adults, adolescents, and children weighing at least 25 kg. It contains abacavir and lamivudine as the active substances and it is given orally.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Abacavir/lamivudine, together with measures to minimise such risks and the proposed studies for learning more about Abacavir/lamivudine's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine’s legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In the case of Abacavir/lamivudine, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of Important Risks and Missing Information

Important risks of Abacavir/lamivudine are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Abacavir/lamivudine. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Table 10: Summary of Safety Concerns

List of important risks and missing information	
Important identified risks	• Abacavir hypersensitivity reaction (including reduced vigilance following HLA-B*-5701 testing)
Important potential risks	• Use in pregnancy
Missing information	• None

II.B Summary of Important Risks

Table 11: Summary of Pharmacovigilance Activities and Risk Minimisation Activities by Safety Concern

Important identified risk: Abacavir hypersensitivity reaction (including reduced vigilance following HLA-B*-5701 testing)	
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.1, 4.3, 4.4 and 4.8. SmPC sections 4.1 and4.4 where advice is given on HLA-B*-5701 testing. PL section 2, 3, and 4. Outer package. Prescription only medicine. Additional risk minimisation measures Healthcare Professional Guide Patient alert card.
Important potential risk: Use in pregnancy	
Risk minimisation measures	Routine risk minimisation measures SmPC sections 4.4, 4.6, and 5.1. PL section 2. Prescription only medicine. Additional risk minimisation measures None
Additional	Additional pharmacovigilance activities:

pharmacovigilance activities	Antiretroviral pregnancy registry in the US. See section II.C of this summary for an overview of the post-authorisation development plan.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which Are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Abacavir/lamivudine.

II.C.2 Other Studies in Post-Authorisation Development Plan

Study short name:

Antiretroviral pregnancy registry (APR) in the US.

Purpose of the study:

Objective of the APR is to detect any major teratogenic effect involving any of the Registry antiretroviral drugs when administered to pregnant women.