Part VI: Summary of the risk management plan

Summary of risk management plan for Abacavir Accord 300 mg film-coated tablets (Abacavir)

This is a summary of the risk management plan (RMP) for Abacavir Accord 300 mg film-coated tablets. The RMP details important risks of Abacavir Accord 300 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Abacavir Accord 300 mg film-coated tablets' risks and uncertainties (missing information).

Abacavir Accord 300 mg film-coated tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on Abacavir Accord 300 mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Abacavir Accord 300 mg film-coated tablets RMP.

I. The medicine and what it is used for

Abacavir Accord is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults, adolescents and children.

The demonstration of the benefit of Abacavir Accord is mainly based on results of studies performed with a twice daily regimen, in treatment-naïve adult patients on combination therapy.

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. Abacavir should not be used in patients known to carry the HLA-B*5701 allele.

It contains abacavir as the active substance and is given orally.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Abacavir Accord 300 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Abacavir Accord 300 mg film-coated tablets risks, are outlined below.

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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 Accord 300 mg film-coated tablets, 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 (if applicable) and signal management activity, 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 Accord 300 mg film-coated tablets 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 Accord 300 mg film-coated tablets. 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).

Important Identified Risks	• ABC hypersensitivity reaction (including reduced vigilance following HLA-B*-5701 testing)
Important Potential Risks	• None

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Missing information	• None

II.B Summary of important risks

Important Identified Risk: ABC hypersensitivity reaction (including reduced vigilance following HLA-B*-5701 testing)	
Risk minimisation measures	Routine risk minimisation measures: Section 4.1, 4.3, 4.4, and 4.8 of Abacavir Accord SmPC and corresponding sections of PIL has information on this safety concern. Other routine risk minimisation measures include; the labelling and the prescription only status of the product. Additional risk minimisation measures: Patient alert card.

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 authorization or specific obligation of Abacavir Accord 300 mg film-coated tablets.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Abacavir Accord 300 mg film-coated tablets as post-authorisation development plan.

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