PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Part VI. A Summary of risk management plan for Abacavir/Lamivudin Vale 600 mg/300 mg Filmtabletten (abacavir/lamivudine)

This is a summary of the risk management plan (RMP) for abacavir/lamivudine (Abacavir/Lamivudin Vale 600 mg/300 mg Filmtabletten). 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/Lamivudin Vale's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

I. The medicine and what it is used for

Abacavir/Lamivudin Vale 600 mg/300 mg Filmtabletten is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults, adolescents and children weighing at least 25 kg. It contains abacavir/lamivudine as the active substance and it is given by oral route.

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

Important risks of Abacavir/Lamivudin Vale, together with measures to minimise such risks and the proposed studies for learning more about Abacavir/Lamivudin Vale’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 public (e.g. with or without prescription) can help to minimises its risks.

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

In addition to these measures, information about adverse events is collected continuously and is regularly analysed, including in PSUR assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.
In the case of abacavir/lamivudine, the routine measures described above are supplemented with additional risk minimisation measures, mentioned under relevant risks below.

II.A List of important risks and missing information

Important risks of Abacavir/Lamivudin Vale are those risks that need special risk management activities to further investigate or minimise them, so that the medicinal product can be safely administered to patients. 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/Lamivudin Vale. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but the definite causal 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/use in special patient populations etc.);

Table 7 Part VI: Summary of safety concerns Abacavir/Lamivudin Vale

List of important risks and missing information	
Important identified risks	ABC hypersensitivity reaction (including reduced vigilance following HLA-B*-5701 testing
Important potential risks	• Use in subjects with moderate/severe hepatic impairment • Ischaemic cardiac events • Risk of shorter time to virological failure • Drug interaction with ribavirin • Drug interaction with tenofovir disoproxil fumarate • Use during pregnancy and breastfeeding • Carcinogenicity and long-term use
Missing information	None

II.B Summary of important risks

The safety information in the approved Product Information is aligned to the reference medicinal product.

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/Lamivudin Vale.

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

Antiretroviral Pregnancy Registry.
Purpose of study: To collect information on the risk of birth defects in patients exposed to abacavir/lamivudine during pregnancy.

Part VI.B Summary of risk management plan for Abacavir/Lamivudine Mylan (abacavir/lamivudine)

This is a summary of the risk management plan (RMP) for abacavir/lamivudine (Abacavir/Lamivudine Mylan). 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 Mylan's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

I. The medicine and what it is used for

Abacavir/Lamivudine Mylan is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults, adolescents and children weighing at least 25 kg. It contains abacavir/lamivudine as the active substance and it is given by oral route.

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

Important risks of Abacavir/Lamivudine Mylan, together with measures to minimise such risks and the proposed studies for learning more about Abacavir/Lamivudine Mylan'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 public (e.g. with or without prescription) can help to minimises its risks.

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

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

In the case of abacavir/lamivudine, the routine measures described above are supplemented with additional risk minimisation measures, mentioned under relevant risks below.

II.A List of important risks and missing information

Important risks of Abacavir/Lamivudine Mylan are those risks that need special risk management activities to further investigate or minimise them, so that the medicinal product can be safely administered to patients. 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 Mylan. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but the definite causal 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/use in special patient populations etc.).

Table 8 Part VI: Summary of safety concerns Abacavir/Lamivudine Mylan

List of important risks and missing information	
Important identified risks	ABC hypersensitivity reaction (including reduced vigilance following HLA-B*-5701 testing
Important potential risks	• Use in subjects with moderate/severe hepatic impairment • Ischaemic cardiac events • Risk of shorter time to virological failure • Drug interaction with ribavirin • Drug interaction with tenofovir disoproxil fumarate • Use during pregnancy and breastfeeding • Carcinogenicity and long-term use
Missing information	None

II.B Summary of important risks

The safety information in the approved Product Information is aligned to the reference medicinal product.

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 Mylan.

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

Antiretroviral Pregnancy Registry.

Purpose of study: To collect information on the risk of birth defects in patients exposed to abacavir/lamivudine during pregnancy.