Part VI: Summary of the risk management plan

Summary of risk management plan for Abacavir/Lamivudine Xiromed (Abacavir sulfate/Lamivudine)

This is a summary of the risk management plan (RMP) for Abacavir/Lamivudine Xiromed. The RMP details important risks of Abacavir/Lamivudine Xiromed, how these risks can be minimised, and how more information will be obtained about Abacavir/Lamivudine Xiromed's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Abacavir/Lamivudine Xiromed is authorised for antiretroviral combination therapy for the treatment of HIV infection in adults, adolescents and children (see SmPC for the full indication). It contains abacavir sulfate and lamivudine as the active substances and it is given by film-coated tablets.

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

Important risks of Abacavir/Lamivudine Xiromed, together with measures to minimise such risks and the proposed studies for learning more about Abacavir/Lamivudine Xiromed'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 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 Xiromed 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 Xiromed. 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).

List of important risks and missing information	
Important identified risks	• Abacavir (ABC) hypersensitivity reaction (including reduced vigilance following HLA-B*-5701 testing)
Important potential risks	• Use in subjects with moderate/severe hepatic impairment • Long term risk of carcinogenicity and long term exposure to NRTIs • Use in pregnancy • Ischaemic cardiac events • Possible interaction of ABC/3TC with tenofovir disoproxil fumarate • Risk of shorter time to virological failure
Missing information	None

II.B Summary of important risks

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

II.C Post-authorisation development plan

Not applicable.

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 Xiromed.

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

There are no studies required for Abacavir/Lamivudine Xiromed.