PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Symtuza (D/C/F/TAF)

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

Symtuza's summary of product characteristics (SmPC) and its package leaflet (PL) provide essential information to healthcare professionals and patients on how Symtuza should be used.

This summary of the RMP for Symtuza should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The Medicine and What it is Used For

Symtuza is authorized for the treatment of human immunodeficiency virus (HIV) type-1 (HIV-1) infection in adults and adolescents (aged 12 years and older with body weight at least 40 kg) (see SmPC for the full indication). It contains darunavir (DRV) (as ethanolate), cobicistat (COBI), emtricitabine (FTC), and tenofovir alafenamide (TAF) (as fumarate) as the active substances and it is given as an oral fixed-dose combination (FDC) tablet (DRV 800 mg, COBI 150 mg, FTC 200 mg, and TAF 10 mg).

Further information about the evaluation of Symtuza’s benefits can be found in Symtuza’s EPAR, including in its plain-language summary, available on the European Medicines Agency (EMA) website, under the medicine’s webpage:
https://www.ema.europa.eu/en/medicines/human/EPAR/symtuza.

II. Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of Symtuza, together with measures to minimize such risks and the proposed studies for learning more about Symtuza's risks, are outlined below.

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

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;
- The authorized 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 (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Benefit-Risk Evaluation Report (PBRER)/Periodic Safety Update Report (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 Symtuza are risks that need special risk management activities to further investigate or minimize 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 Symtuza. 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 (eg, on the long-term use of the medicine);

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B. Summary of Important Risks

Not applicable. There are no important identified risks, important potential risks, or missing information.

II.C. Postauthorization Development Plan

II.C.1. Studies Which are Conditions of the Marketing Authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Symtuza.

II.C.2. Other Studies in Postauthorization Development Plan

There are no studies required for Symtuza.