Summary of risk management plan for TRIUMEQ

This is a summary of the RMP for TRIUMEQ. The RMP details important risks of TRIUMEQ, how these risks can be minimised, and how more information will be obtained about the TRIUMEQ risks and uncertainties (missing information).

The TRIUMEQ summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how TRIUMEQ should be used.

This summary of the RMP for TRIUMEQ 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 TRIUMEQ RMP.

I. The medicine and what it is used for

TRIUMEQ is authorized for the treatment of HIV infected adults, adolescents above 12 years of age weighing at least 40 kg. (see SmPC for the full indication). It contains DTG, ABC and 3TC as the active substance and it is given by oral route.

Further information about the evaluation of the benefits of TRIUMEQ can be found in the TRIUMEQ EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:

https://www.ema.europa.eu/en/medicines/human/EPAR/triumeq

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

Important risks of TRIUMEQ, together with measures to minimise such risks and the proposed studies for learning more about Triumeq'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 TRIUMEQ 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 PBRER assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of TRIUMEQ is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of TRIUMEQ 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 TRIUMEQ. 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).

TRIUMEQ is a medicine that does not contain a new active substance. The identified and potential risks for TRIUMEQ have been taken from the approved TIVICAY (dolutegravir (DTG)) and Ziagen (ABC) or Kivexa (ABC/3TC) RMPs. No new risks have been identified for TRIUMEQ.

Summary of safety concerns The safety profile of DTG taken in combination with ABC and 3TC is consistent with the safety profiles of the single agents, and no additional risks or safety issues due to combination therapy have been identified.	
Important identified risks	**ABC** • Hypersensitivity reactions
Important potential risks	**DTG** • Neural tube defects
Missing information	• Use in pregnancy/ breastfeeding

II.B Summary of important risks

TRIUMEQ is a medicine that does not contain a new active substance. The identified and potential risks for TRIUMEQ have been taken from the approved TIVICAY (dolutegravir) and ZIAGEN (ABC) or KIVEXA (ABC/3TC) RMPs. No new risks have been identified for TRIUMEQ.

The safety information in the Product Information for TRIUMEQ is aligned to the reference medicinal products (TIVICAY and ZIAGEN or KIVEXA).

Additional pharmacovigilance and additional risk minimisation activities (where applicable) for TRIUMEQ are provided in the table below:

Important identified risk (ABC): Hypersensitivity	
Additional pharmacovigilance activities	None
Additional risk minimisation activities	Each pack of TRIUMEQ medication contains an Alert Card for patients and information on the risk of HSR with ABC in the Patient Information Leaflet.

Important potential risk: Neural tube defects	
Additional Risk minimisation measures	Direct health care professional communication completed in 2018
Additional pharmacovigilance activities	Antiretroviral Pregnancy Registry Study 208613 -DOLOMITE EPPICC Study Study 208759 -DOLOMITE NEAT ID Network Study

Missing Information: Use in pregnancy	
Additional pharmacovigilance activities	Antiretroviral Pregnancy Registry Study 208613 -DOLOMITE EPPICC Study Study 208759 -DOLOMITE NEAT ID Network Study

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 TRIUMEQ.

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

Study/Activity (including study number)	Objectives	Safety concerns/efficacy issue addressed	Status	Planned date for submission of (interim and) final study results
Antiretroviral Pregnancy Registry	Monitors prenatal exposures to antiretroviral drugs to detect a potential increase in the risk of birth defects through a prospective exposure-registration	Use in pregnancy	Ongoing	A registry interim report is prepared semi-annually summarising the aggregate data. Data from the APR will be presented in the PBRER.
Study 208613 DOLOMITE EPPICC Study	Assess “real-world” maternal and foetal outcomes following DTG use during pregnancy and to describe patterns of DTG utilization	Use in pregnancy, NTDs DTG exposure relative to conception will be captured in this study, thus enabling assessment of pre-conception exposures along with first, second and third trimester exposures.	Ongoing	Final Report June 2023

Study/Activity (including study number)	Objectives	Safety concerns/efficacy issue addressed	Status	Planned date for submission of (interim and) final study results
Study 208759 DOLOMITE NEAT ID Network Study	To assess the safety and effectiveness of DTG in pregnancy in the NEAT-ID network of approximately 40 sites across Europe.	Use in pregnancy, NTDs DTG exposure relative to conception will be captured in this study, thus enabling assessment of pre-conception exposures along with first, second and third trimester exposures.	Ongoing	Final Report October 2023