



## **Swiss Summary of the Risk Management Plan (RMP)**

**for**

**BIKTARVY®**

**(Bictegravir/Emtricitabine/Tenofovir Alafenamide)**

Version 2.0 (April 2020)

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## **1. SUMMARY OF RISK MANAGEMENT PLAN FOR BIKTARVY (BICTEGRAVIR/EMTRICITABINE/ TENOFOVIR ALAFENAMIDE)**

The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine.

The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimize them.

The RMP summary of Biktarvy is a concise document and does not claim to be exhaustive. As the RMP is an international document, the summary might differ from the “Arzneimittelinformation” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization. Please note that the reference document which is valid and relevant for the effective and safe use of Biktarvy in Switzerland is the “Arzneimittelinformation” (see [www.swissmedicinfo.ch](http://www.swissmedicinfo.ch)) approved and authorized by Swissmedic.

Gilead Sciences Ireland UC is fully responsible for the accuracy and correctness of the content of the here published summary RMP of Biktarvy.

### **1.1. The Medicine and What it is Used For**

Biktarvy is authorized for the treatment of adults infected with human immunodeficiency virus-1 (HIV-1) (see SmPC for the full indication). It contains bicittegravir (BIC; B), emtricitabine (FTC; F) and tenofovir alafenamide (TAF) as the active substances and it is given orally.

Further information about the evaluation of Biktarvy's benefits can be found in Biktarvy's 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/biktarvy>.

### **1.2. Risks Associated with the Medicine and Activities to Minimize or Further Characterize the Risks**

Important risks of Biktarvy, together with measures to minimize such risks and the proposed studies for learning more about Biktarvy'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 package leaflet 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 public (e.g. 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 safety update report (PSUR) 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 Biktarvy is not yet available, it is listed under ‘missing information’ below.

### 1.2.1. List of Important Risks and Missing Information

Important risks of Biktarvy are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered. 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 Biktarvy. 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).

**Table 1-1. List of Important Risks and Missing Information**

<b>Important Identified Risks</b>	None
<b>Important Potential Risks</b>	None
<b>Missing Information</b>	Safety in pregnancy and lactation

### 1.2.2. Summary of Important Risks

**Table 1-2. Summary of Important Risk(s) and Missing Information**

<b>Missing information</b>	<b>Safety in pregnancy and lactation</b>
<b>Risk Minimization Measure(s)</b>	Routine risk communication: SmPC section 4.6 PL section 2
<b>Additional Pharmacovigilance activities</b>	Antiretroviral Pregnancy Registry See Section 1.2.3 of this summary for an overview of the post-authorization development plan.

### **1.2.3. Post-authorization Development Plan**

#### **1.2.3.1. Studies which are Conditions of the Marketing Authorization**

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

#### **1.2.3.2. Other Studies in Post-Authorization Development Plan**

**Table 1-3. Other Studies in Post-Authorization Development Plan**

<b>Short Study Name</b>	<b>Purpose of the Study</b>
<b>Antiretroviral Pregnancy Registry (APR)</b>	To collect information on the risk of birth defects with antiretroviral drugs, including Biktarvy, during pregnancy.

This summary was last updated in April 2020.