EU RISK MANAGEMENT PLAN
For
Emtricitabine/Tenofovir disoproxil Mylan (emtricitabine/tenofovir disoproxil)
Version 10.1

RMP Version to be Assessed as Part of this Application:

RMP Version Number	10.1
Data Lock Point for this RMP	14-Jul-2026
Date of Final Sign Off	24-Aug-2026
Rationale for Submitting an Updated RMP	• RMP updated in line with Risk Management Plan v20.0 of the reference product, Truvada® - dated 28-Oct-2025 published on the EMA website on 18-Nov-2025. • EMA remarks at the time of approval of RMP version 9.1 for MAH's consideration in the next update. • RMP amended in line with assessor comments for Type IB variation assessment report for Emtricitabine / Tenofovir disoproxil procedure number EMEA/H/C/004050, dated 14-Jul-2026
Summary of Significant Changes in this RMP	The following significant changes were made in the current RMP in line with Truvada® RMP v20.0: • Removal Safety in pregnancy and lactation (in relation to tenofovir" as missing information. • Removal of additional pharmacovigilance activities of: Antiretroviral pregnancy registry. • Removal of targeted follow-up questionnaires for bone and renal risks.

Other RMP Versions Under Evaluation:

RMP Version Number	Not applicable
Submitted On	Not applicable
Procedure Number	Not applicable

Details of the Current RMP:

Version Number	9.1
Approved with Procedure	Centralized, EMEA/H/C/004050/IB/0024/G
Date of Approval (Opinion Date)	05-Jul-2023

QPPV name: Andrea Oliva, PhD, EEA QPPV

QPPV oversight declaration: The content of this RMP has been reviewed and approved by the marketing authorisation holder´s QPPV. The electronic signature is available on file.

Table of Contents

LIST OF TABLES

LIST OF ABBREVIATIONS

Abbreviation	Definition
ADR	Adverse Drug Reaction
ATC	Anatomical Therapeutic Chemical Classification System
CHMP	Committee for Medicinal Products for Human Use
DLP	Data Lock Point
EEA	European Economic Area
EPAR	European Public Assessment Report
EU	European Union
EURD	European Union Reference Date
HBV	Hepatitis B Virus
HCP	Healthcare Professional
HIV	Human Immunodeficiency Virus
ICSR	Individual Case Safety Report
MAH	Marketing Authorization Holder
NRTIs	Nucleoside Reverse Transcriptase Inhibitors
PL	Package Leaflet
PRAC	Pharmacovigilance Risk Assessment Committee
PrEP	Pre-Exposure Prophylaxis
PSUR	Periodic Safety Update Report
PTY	Patient Treatment Years
QPPV	Qualified Person for Pharmacovigilance
RMMs	Risk Minimisation Measures
RMP	Risk Management Plan
SmPC	Summary of Product Characteristics

PART I: PRODUCT(S) OVERVIEW

Table 1: Part 1.1-Product Overview

Active Substances (INN or Common Name)	Emtricitabine and Tenofovir disoproxil
Pharmacotherapeutic Groups (ATC Code)	Antiviral for systemic use; antivirals for treatment of HIV infections, combinations. ATC code: J05AR03
Marketing Authorisation Holder	Mylan Pharmaceuticals Ltd
Medicinal Products to Which this RMP Refers	01
Invented Name in the European Economic Area (EEA)	Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablets
Marketing Authorisation Procedure	Centralized: EMEA/H/C/004050
Brief Description of the Product	Pharmacotherapeutic group: Antiviral for systemic use; antivirals for treatment of HIV infections, combinations. ATC code: J05AR03. Emtricitabine is a nucleoside analogue of cytidine. Tenofovir disoproxil is converted in vivo to tenofovir, a nucleoside monophosphate (nucleotide) analogue of adenosine monophosphate. Both emtricitabine and tenofovir have activity that is specific to human immunodeficiency virus (HIV 1 and HIV 2) and hepatitis B virus. Emtricitabine and tenofovir are phosphorylated by cellular enzymes to form emtricitabine triphosphate and tenofovir diphosphate, respectively. In vitro studies have shown that both emtricitabine and tenofovir can be fully phosphorylated when combined together in cells. Emtricitabine triphosphate and tenofovir diphosphate competitively inhibit HIV 1 reverse transcriptase, resulting in DNA chain termination. Both emtricitabine triphosphate and tenofovir diphosphate are weak inhibitors of mammalian DNA polymerases and there was no evidence of toxicity to mitochondria *in vitro* and *in vivo*.
Hyperlink to the Product Information:	Please refer to section 1.3.1 of the dossier
Indication(s) in the EEA	Current: <u>Treatment of HIV-1 infection:</u> Emtricitabine/Tenofovir disoproxil Mylan is indicated in antiretroviral combination therapy for the treatment of HIV-1 infected adults.

	Emtricitabine/Tenofovir disoproxil Mylan is also indicated for the treatment of HIV-1 infected adolescents, with NRTI resistance or toxicities precluding the use of first line agents. Pre-exposure prophylaxis (PrEP): Emtricitabine/Tenofovir disoproxil Mylan is indicated in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents at high risk. Proposed: Not applicable
Dosage in the EEA	Current: Emtricitabine/Tenofovir disoproxil Mylan should be initiated by a physician experienced in the management of HIV infection. Posology *Treatment of HIV in adults and adolescents aged 12 years and older, weighing at least 35 kg:* One tablet, once daily. *Prevention of HIV in adults and adolescents aged 12 years and older, weighing at least 35kg:* One tablet, once daily. Separate preparations of emtricitabine and tenofovir disoproxil are available for treatment of HIV-1 infection if it becomes necessary to discontinue or modify the dose of one of the components of Emtricitabine/Tenofovir disoproxil Mylan. Please refer to the Summary of Product Characteristics for these medicinal products. If a dose of emtricitabine/tenofovir disoproxil is missed within 12 hours of the time it is usually taken, emtricitabine/tenofovir disoproxil should be taken as soon as possible and the normal dosing schedule should be resumed. If a dose of emtricitabine/tenofovir disoproxil is missed by more than 12 hours and it is almost time for the next dose, the missed dose should not be taken, and the usual dosing schedule should be resumed. If vomiting occurs within 1 hour of taking Emtricitabine/Tenofovir disoproxil Mylan, another tablet should be taken. If vomiting occurs more than 1 hour after taking Emtricitabine/Tenofovir disoproxil Mylan a second dose should not be taken. Method of administration Oral administration. It is preferable that Emtricitabine/Tenofovir disoproxil Mylan is taken with food. The tablet can be

	disintegrated in approximately 100 mL water, orange juice or grape juice and taken immediately. Proposed: Not applicable
Pharmaceutical Form(s) and Strengths	Current: Each film coated tablet contains 200 mg of emtricitabine and 245 mg of tenofovir disoproxil (as maleate). Proposed: Not applicable
Is the Product Subject to Additional Monitoring in the EU?	No

PART II: SAFETY SPECIFICATION

Part II: Module SI - Epidemiology of the Indication(s) and Target Population(s)

Not applicable.

Part II: Module SII - Non-clinical Part of the Safety Specification

Not applicable.

Part II: Module SIII - Clinical Trial Exposure

Not applicable.

Part II: Module SIV - Populations Not Studied in Clinical Trials

Not applicable.

Part II: Module SV - Post-authorisation Experience

SV.1 Post-authorisation Exposure

Not applicable.

Part II: Module SVI - Additional EU Requirements for the Safety Specification

Not applicable.

Part II: Module SVII - Identified and Potential Risks

SVII.1 Identification of Safety Concerns in the Initial RMP Submission

The identified and potential risks for this generic medicine are aligned with the risks of the reference medicinal product (Truvada 200 mg/245 mg film-coated tablets, Gilead Sciences Ltd).

SVII.1.1. Risks Not Considered Important for Inclusion in the List of Safety Concerns in the RMP

The identified and potential risks for this generic medicine are aligned with the risks of the reference medicinal product (Truvada 200 mg/245 mg film-coated tablets, Gilead Sciences Ltd).

SVII.1.2. Risks Considered Important for Inclusion in the List of Safety Concerns in the RMP

The identified and potential risks for this generic medicine are aligned with the risks of the reference medicinal product (Truvada 200 mg/245 mg film-coated tablets, Gilead Sciences Ltd).

SVII.2 New Safety Concerns and Reclassification with a Submission of an Updated RMP

The MAH is proposing to update its RMP in line with the reference medicinal product RMP v20.0 Truvada® published on the EMA website on 18-Nov-2025 to remove the following safety concern: Safety in pregnancy

and lactation (in relation to tenofovir).

SVII.3 Details of Important Identified Risks, Important Potential Risks, and Missing Information

SVII.3.1. Presentation of Important Identified Risks and Important Potential Risks

The identified and potential risks for this generic medicine are aligned with the risks of the reference medicinal product (Truvada 200 mg/245 mg film-coated tablets, Gilead Sciences Ltd).

SVII.3.2. Presentation of the Missing Information

The identified and potential risks for this generic medicine are aligned with the risks of the reference medicinal product (Truvada 200 mg/245 mg film-coated tablets, Gilead Sciences Ltd).

Part II: Module SVIII - Summary of the Safety Concerns

Table 2: SVIII- Summary of safety concerns

Important Identified Risks	• HIV-1 acquisition, including infection resulting from non-adherence (pre-exposure prophylaxis (PrEP) indication) • Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication)
Important Potential Risks	None.
Missing Information	None.

PART III: PHARMACOVILIGANCE PLAN (INCLUDING POST-AUTHORISATION SAFETY STUDIES)

III.1 Routine Pharmacovigilance Activities

The MAH is planning to use specific adverse reaction follow-up questionnaires to obtain structured information on reported suspected adverse reactions of special interest, therefore, the following routine pharmacovigilance activities beyond ADRs reporting and signal detection are in place for the following risks:

Risk	**Targeted follow-up questionnaire's name**
HIV-1 acquisition, including infection resulting from non-adherence (PrEP indication)	- Targeted Follow Up Form for Emtricitabine/Tenofovir–Lack of efficacy for PrEP
Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication)	- Targeted Follow Up Form for Emtricitabine/Tenofovir – Lack of efficacy for PrEP

The form is provided in Annex 4 - Specific Adverse Drug Reaction Follow-up Forms of the RMP.

III.2 Additional Pharmacovigilance Activities

As current routine pharmacovigilance activities are sufficient, no additional pharmacovigilance activities are recommended.

III.3 Summary Table of Additional Pharmacovigilance Activities

None.

PART IV: PLANS FOR POST-AUTHORISATION EFFICACY STUDIES

Not applicable.

PART V: RISK MINIMISATION MEASURES

Risk Minimisation Plan

The safety information in the proposed product information is aligned to the reference medicinal product (Truvada 200 mg/245 mg film-coated tablets, Gilead Sciences Ltd).

V.1 Routine Risk Minimisation Measures

Table 3: Part V.1- Description of routine risk minimisation measures by safety concern

Safety Concern	Routine Risk Minimisation Activities
HIV-1 acquisition, including infection resulting from non-adherence (PrEP indication)	Routine risk communication: SmPC Section 4.4 PL Sections 2 and 3 Routine risk minimisation activities recommending specific clinical measures to address the risk: SmPC Section 4.4 Warning that HIV-1 uninfected individuals should be counselled at frequent intervals to strictly adhere to the recommended daily dosing schedule with Emtricitabine/Tenofovir disoproxil Mylan. Other risk minimisation measures beyond the Product Information: Medicine's legal status: Restricted medical prescription.
Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication)	Routine risk communication: SmPC: Sections 4.3 and 4.4 PL: Section 2 Routine risk minimisation activities recommending specific clinical measures to address the risk: SmPC Section 4.4 Warning on confirming individuals to be HIV-negative at frequent intervals (e.g. at least every 3 months) prior to initiating Emtricitabine/Tenofovir disoproxil Mylan and at frequent intervals (e.g. at least every 3 months) while taking Emtricitabine/Tenofovir disoproxil Mylan for PrEP. Other risk minimisation measures beyond the Product Information: Medicine's legal status: Restricted medical prescription.

V.2 Additional Risk Minimisation Measures

This medicine has additional risk minimisation measures for the following risks:

Safety concern	Risk minimisation measures
HIV-1 acquisition, including infection resulting from non-adherence (PrEP indication)	• PrEP Educational brochure for prescribers • PrEP Checklist for prescribers • PrEP educational brochure for the individual at risk

Safety concern	Risk minimisation measures
	• PrEP reminder card
Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication)	• PrEP Educational brochure for prescribers • PrEP Checklist for prescribers • PrEP educational brochure for the individual at risk • PrEP reminder card

Objectives of Additional Risk Minimisation Activities:

To address the risks of HIV-1 acquisition, including infection resulting from non-adherence (PrEP indication) and development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication) the MAH proposes educational brochure for prescribers and checklist for prescribers to educate HCPs about specific risks, their early symptoms and the best course of action to be taken when these appear, beyond the recommendation contained in the Product Information.

To address the risks of HIV-1 acquisition in HIV-1 negative subjects (PrEP indication) and development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication), the MAH proposes PrEP educational brochure for the individual at risk and PrEP reminder card, to ensure that special information regarding the patient's current therapy and its important risks (e.g. potential life-threatening interactions with other therapies) is held by the patient at all times and reaches the relevant HCP as appropriate. It contains the minimum necessary information to convey the key minimisation messages and the required mitigating action, in any circumstances, including emergency.

Rationale for the Additional Risk Minimisation Activity:

The MAH considers it is necessary to educate HCPs and patients/caregivers about specific risks, their early symptoms and the best course of action to be taken when these appear, beyond the recommendation contained in the Product Information.

Target Audience and Planned Distribution Path:

HCP/patients/carers

Plans for Evaluating the Effectiveness of the Interventions and Criteria for Success:

Effectiveness of additional RMMs will be evaluated on annual basis after MA approval.

Rationale for Proposing to Remove Additional Risk Minimisation Measures:

Following the removal of the safety concern Renal toxicity in line with the Risk Management Plan Summary of the reference product, Truvada®, the MAH is removing the additional risk minimisation measure HIV paediatric renal educational brochure for physicians as well form the RMP.V.3 Summary Table of Pharmacovigilance and Risk Minimisation Activities by Safety Concern

V.3 Summary of Risk minimisation measures

Table 4: Part V.3- Summary table of pharmacovigilance activities and risk minimisation activities by safety concern

Safety Concern	Risk Minimisation Measures	Pharmacovigilance Activities
Important identified risks		
HIV-1 acquisition, including infection resulting from non-adherence (PrEP indication)	Routine risk minimization measures: SmPC Section 4.4 PL Sections 2 and 3 Additional risk minimisation measures: • PrEP Educational brochure for prescribers • PrEP Checklist for prescribers • PrEP educational brochure for the individual at risk • PrEP reminder card	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: Targeted questionnaire for Lack of efficacy for PrEP Additional pharmacovigilance activities: None
Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication)	Routine risk minimization measures: SmPC Sections 4.3 and 4.4 PL Section 2 Additional risk minimisation measures: • PrEP Educational brochure for prescribers • PrEP Checklist for prescribers • PrEP educational brochure for the individual at risk • PrEP reminder card	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: Targeted questionnaire for Lack of efficacy for PrEP Additional pharmacovigilance activities: None

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablets (Emtricitabine/Tenofovir disoproxil)

This is a summary of the risk management plan (RMP) for Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablets. The RMP details important risks of Emtricitabine/Tenofovir disoproxil, how these risks can be minimised, and how more information will be obtained about Emtricitabine/Tenofovir disoproxil's risks and uncertainties (missing information).

Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

This summary of the RMP for Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablets should be read in the context of all the 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 Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablet's RMP.

I. The Medicine and What it is Used For

Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablets is authorised as antiretroviral combination therapy for the treatment of HIV-1 infected adults. Emtricitabine/Tenofovir disoproxil Mylan is also indicated for the treatment of HIV-1 infected adolescents, with NRTI resistance or toxicities precluding the use of first line agents. It is also indicated in combination with safer sex practices for pre-exposure prophylaxis to reduce the risk of sexually acquired HIV-1 infection in adults and adolescents at high risk. It contains Emtricitabine/Tenofovir disoproxil as the active substance and it is given by oral route.

Further information about the evaluation of Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablet benefits can be found in Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablet’s EPAR, including in its plain-language summary, available on the EMA website, under the medicine’s webpage.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablet'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 the case of Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablet, these routine measures are supplemented with additional risk minimisation measures, mentioned under relevant risks below.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, including 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 Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablet is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by 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 Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablet. 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 5: Part VI.1- Summary of safety concerns

List of Important Risks and Missing Information	
Important Identified Risks	• HIV-1 acquisition, including resulting from non-adherence (pre-exposure prophylaxis (PrEP) indication) • Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication)
Important Potential Risks	None
Missing Information	None

II.B Summary of Important Risks

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

Table 6: Part VI.2- HIV-1 acquisition, including infection resulting from non-adherence (PrEP indication)

Evidence for Linking the Risk to the Medicine	In line with the reference RMP, this safety concern has been classified as an important identified risk.
Risk Factors and Risk Groups	Subjects with poor treatment compliance
Risk Minimisation Measures	Routine risk communication: SmPC Section 4.4 PL Section 2 and Section 3

	Routine risk minimisation activities recommending specific clinical measures to address the risk: SmPC Section 4.4 Warning that HIV-1 uninfected individuals should be counselled at frequent intervals to strictly adhere to the recommended daily dosing schedule with Emtricitabine/Tenofovir disoproxil Mylan. Other risk minimisation measures beyond the Product Information: Medicine's legal status: Restricted medical prescription. Additional risk minimisation measures: • PrEP Educational brochure for prescribers • PrEP Checklist for prescribers • PrEP educational brochure for the individual at risk • PrEP reminder card

Table 7: Part VI.2- Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication)

Evidence for Linking the Risk to the Medicine	In line with the reference RMP, this safety concern has been classified as an important identified risk.
Risk Factors and Risk Groups	Subjects with undiagnosed HIV-1 on emtricitabine/tenofovir disoproxil for PrEP.
Risk Minimisation Measures	Routine risk communication: SmPC: Sections 4.3 and 4.4 PL: Section 2 Routine risk minimisation activities recommending specific clinical measures to address the risk: SmPC Section 4.4 Warning on confirming individuals to be HIV-negative prior to initiating Emtricitabine/Tenofovir disoproxil Mylan and at frequent intervals (e.g. at least every 3 months) while taking for Emtricitabine/Tenofovir disoproxil Mylan for PrEP. Other risk minimisation measures beyond the Product Information: Medicine's legal status: Restricted medical prescription. Additional risk minimisation measures: • PrEP Educational brochure for prescribers • PrEP Checklist for prescribers • PrEP educational brochure for the individual at risk • PrEP reminder card

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 Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablets.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Emtricitabine/Tenofovir disoproxil Mylan 200 mg/245 mg film coated tablets.

PART VII: ANNEXES

Annex 4 - Specific Adverse Drug Reaction Follow-up Forms

Targeted follow-up questionnaires for the following safety concerns:

Risk	Targeted follow-up questionnaire's name
HIV-1 acquisition in HIV-1 negative subjects (PrEP indication)	- Targeted Follow Up Form for Emtricitabine/Tenofovir – Lack of efficacy for PrEP
Development of resistance in patients with unrecognized or acute HIV-1 infection (PrEP indication)	- Targeted Follow Up Form for Emtricitabine/Tenofovir – Lack of efficacy for PrEP

Targeted Follow Up Form for Emtricitabine/Tenofovir – Lack of efficacy for PrEP

You have reported an adverse reaction(s) of [Lack of efficacy with emtricitabine/tenofovir for PrEP] for [emtricitabine/tenofovir]. This questionnaire is being sent to you for obtaining valuable additional information about the reported case to thoroughly evaluate the relation to [emtricitabine/tenofovir] exposure. The Questionnaire is already prefilled with all the available information collected at the time of the initial report, only additional information should be filled in. By providing as detailed information as possible, you can make a useful contribution to the safety of [emtricitabine/tenofovir].

1. Patients Details:

Patient's Initials	
Age/Date of birth	
Gender	
Weight	
Height	

2. Drug information at the time of event:

Tradename	
Strength	
Batch number	
Expiry date	
Route of administration	
Dose	
Dose frequency	

Start date	
Stop date	
Onset date for event	

3. Please provide information below for the reported event. (Please provide additional information where possible.)

a). Please provide the start date of PrEP (DD/MMM/YYYY):

b). Please provide lot number, if available:

c). Was the individual tested for HIV prior to starting PrEP?

☐ No

☐ Yes Date: Day/Month/Year Type of HIV test used:

Result:

Antigen

☐ Positive

☐ Negative

☐ result not available

Antibody

☐ Positive

☐ Negative

☐ result not available

d). Was the individual's HBV status confirmed before starting emtricitabine/tenofovir?

☐ yes Result:

☐ no

e) What was the individual's ex at birth:

☐ male

☐ female

f) What is the individual's sexual behaviour pattern:

☐ Man who has sex with men

☐ Transgender woman who has sex with men

☐ Man who has sex with women

☐ Woman who has sex with men

☐ Woman who has sex with women

☐ Other, please specify:

g). What was the reason for prescribing PrEP (check all that apply)?

☐ inconsistent or no condom use

☐ unsafe intravenous drug use

☐ Partner is infected with HIV

☐ Exchange of sex for commodities (such as money, food, or shelter)

☐ partner/multiple partners known to be from a high HIV prevalence area OR social network

☐ sex under the use of recreational drugs (chemsex)

☐ Other, please specify:

h). Was the individual prescribed emtricitabine/tenofovir once-daily?

☐ yes

☐ no If not, what was the reason?

i) Was the individual counselled about safe sex practices?

☐ Yes

☐ No

j). Was the individual practicing safe sex before the reported HIV seroconversion, including using condoms consistently and correctly?

☐ Yes

☐ No

k). How frequently was the individual's HIV status tested?

☐ Every month

☐ Every 3 months

☐ Less frequently than every 3 months

☐ Other, please specify:

Please provide the HIV test results in the table below.

Date (Day/Month/Year)	HIV status test	Genotype/phenotype testing
Prior to initiating Emtricitabine/tenofovir PREP		
While taking Emtricitabine/tenofovir PREP (prior to reported HIV seroconversion)		
At time of reported HIV seroconversion and subsequently		

l). For patients with mutation(s), was the mutation(s):

☐ acquired during emtricitabine/tenofovir for PrEP use. Please specify clinical reasoning:

☐ transmitted. Please specify clinical reasoning:

☐ unknown

m) Was the individual tested for other sexually transmitted infections (e.g. gonorrhoea, chlamydia, HPV)?

☐ No

☐ Yes

Which STIs was the individual tested for? Please specify:

How frequently was the individual tested?

☐ Every month

☐ Every 3 months

☐ Less frequently than every 3 months

☐ Other, please specify:

n). Was the individual adherent to PrEP as prescribed?

☐ Yes

☐ No

If no, please estimate the individual's degree of non-adherence with treatment:

The individual missed on average X doses per week and missed an average of X doses per month

What was the reason the individual missed doses/didn't adhere to the prescribing dosing schedule?

☐ The individual wasn't willing to take emtricitabine/tenofovir disoproxil daily. What was the reason?

☐ The individual decided to stop taking emtricitabine/tenofovir disoproxil. What was the reason?

When? (Day/Month/Year)

☐ The individual forgot to take emtricitabine/tenofovir disoproxil

☐ The individual was experiencing side effects to emtricitabine/tenofovir disoproxil. What was the side effect?

☐ The individual didn't get a refill on time

☐ The individual lost the medication

☐ The individual didn't want other to know he/she was taking emtricitabine/tenofovir disoproxil for PREP

☐ The individual experienced/was aware of negative reactions or opinions with regards to PrEP use (e.g. verbal abuse/comments)

☐ Other, please specify:

o). Was PrEP stopped after HIV seroconversion was confirmed?

☐ Yes, please provide stop date (Day/Month/Year):

☐ No Please list any other anti-retroviral therapies that were initiated after seroconversion:

p). Please specify the individual's concomitant medications (including any herbal therapy):

☐ None

☐ Unknown

4. Outcome of event:

☐ Recovered/resolved	☐ Not recovered/Not resolved
☐ Resolved with sequelae	☐ Fatal
☐ Unknown	☐ Other

If 'Other', please specify: _____

5. Reporter's Details:

I certify that this Questionnaire is accurate and truthful to the best of my knowledge and does not contain any false, fictitious, or fraudulent statements.

Name: Sign

Occupation: Date:

Please be aware that information provided to Mylan relating to you, may be used to comply with applicable laws and regulations. Mylan processes your personal or sensitive data in accordance with applicable data protection laws and the Mylan Privacy Statement, available to you either on https://www.viatris.com/en/viatris-privacy-notice or upon request.

Additional Information:

Annex 6 - Details of Proposed Additional Risk Minimisation Activities (If Applicable)

The Marketing Authorisation Holder (MAH) shall ensure that all physicians who are expected to prescribe/use Emtricitabine/Tenofovir disoproxil Mylan in adults and adolescents for PrEP are provided with a physician educational pack containing the Summary of Product Characteristics and an appropriate educational brochure, as detailed below:

- PrEP educational brochure for prescribers entitled 'Important Safety Information for Prescribers About Emtricitabine/Tenofovir disoproxil Mylan for a Pre-exposure Prophylaxis (PrEP) Indication'
- PrEP Checklist for prescribers
- PrEP educational brochure for the individual at risk entitled 'Important Information About Emtricitabine/Tenofovir disoproxil Mylan to Reduce the Risk of getting Human Immunodeficiency Virus (HIV) Infection'
- PrEP reminder card

PrEP educational brochure for prescribers:

- Reminder of the key safety information regarding the use of Emtricitabine/Tenofovir disoproxil Mylan for PrEP
- Reminder of factors to help identify individuals at high risk of acquiring HIV-1
- Reminder on the risk of development of HIV-1 drug resistance in undiagnosed HIV-1–Infected individuals
- Provides safety information on adherence, HIV testing, renal, bone and HBV status.

PrEP Checklist for prescribers:

- Reminders for evaluations/counselling at the initial visit and follow-up.

PrEP educational brochure for the individual at risk (to be provided by healthcare provider [HCP]):

- Reminders on what the individual should know before and while taking Emtricitabine/Tenofovir disoproxil Mylan to reduce the risk of getting HIV infection
- Reminder on the importance of strict adherence to the recommended dosing regimen
- Provides information on how to take Emtricitabine/Tenofovir disoproxil Mylan
- Provides information on the possible side effects
- Provides information on how to store Emtricitabine/Tenofovir disoproxil Mylan.

PrEP reminder card for the individual at risk (to be provided by HCP):

- Reminders to adhere to the dosing schedule
- Reminder to attend scheduled clinic visits.