Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Emtricitabine/Rilpivirine/Tenofovir Alafenamide 200 mg/25 mg/25 mg film-coated tablets

emtricitabine; rilpivirine; tenofovir alafenamide

PL 04569/1886

GENERICS (UK) LIMITED

LAY SUMMARY

Emtricitabine/Rilpivirine/Tenofovir Alafenamide 200 mg/25 mg/25 mg film-coated tablets
emtricitabine; rilpivirine; tenofovir alafenamide

This is a summary of the Public Assessment Report (PAR) for Emtricitabine/Rilpivirine/Tenofovir Alafenamide 200 mg/25 mg/25 mg film-coated tablets. It explains how this product was assessed and its authorisation recommended, as well as its conditions of use. It is not intended to provide practical advice on how to use this product.

This product will be referred to as Emtricitabine/Rilpivirine/Tenofovir Alafenamide in this lay summary for ease of reading.

This application was approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the European Medicines Agency (EMA) , with the procedure number EMEA/H/C/006491. The procedure followed route A.

This application was approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended).

This product is a generic medicine. This means that this medicine is the same as, and considered interchangeable with, a reference medicine already authorised, called Odefsey 200 mg/25 mg/25 mg film-coated tablets.

For practical information about using Emtricitabine/Rilpivirine/Tenofovir, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Emtricitabine/Rilpivirine/Tenofovir and what is it used for?
Emtricitabine/Rilpivirine/Tenofovir Alafenamide is used in adults and adolescents aged 12 years and older, who weigh at least 35 kg.

How does Emtricitabine/Rilpivirine/Tenofovir work?
Emtricitabine/Rilpivirine/Tenofovir Alafenamide is an antiviral medicine used to treat infection by the Human Immunodeficiency Virus (HIV). It is a single tablet that contains a combination of three active substances: emtricitabine, rilpivirine and tenofovir alafenamide. Each of these active substances works by interfering with an enzyme called ‘reverse transcriptase’, which is essential for the HIV-1 virus to multiply.

Emtricitabine/Rilpivirine/Tenofovir Alafenamide reduces the amount of HIV in the body. This will improve patient’s immune system and reduce the risk of developing illnesses linked to HIV infection.

How is Emtricitabine/Rilpivirine/Tenofovir used?
The pharmaceutical form of this medicine is film-coated tablets and the route of administration is oral (by mouth).

Due to the high-level of detail in the usage instructions it is best to refer directly to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website, for information on how Emtricitabine/Rilpivirine/Tenofovir is used.

This medicine can only be obtained with a prescription. The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Emtricitabine/Rilpivirine/Tenofovir have been shown in studies?
Because Emtricitabine/Rilpivirine/Tenofovir are generic medicines, studies in healthy volunteers have been limited to tests to determine that they are bioequivalent to the reference medicines. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Emtricitabine/Rilpivirine/Tenofovir?
For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

Because Emtricitabine/Rilpivirine/Tenofovir is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are considered to be the same as the reference medicine.

Why was Emtricitabine/Rilpivirine/Tenofovir approved?
It was concluded that, Emtricitabine/Rilpivirine/Tenofovir has been shown to be bioequivalent to the reference medicine. Therefore, the MHRA decided that, as for the reference medicine, the benefits are greater than the risks and recommended that it can be approved for use.

Emtricitabine/Rilpivirine/Tenofovir has been authorised with the condition to perform further studies. See section below "What measures are being taken to ensure the safe and effective use of Emtricitabine/Rilpivirine/Tenofovir?"

What measures are being taken to ensure the safe and effective use of Emtricitabine/Rilpivirine/Tenofovir?
As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Emtricitabine/Rilpivirine/Tenofovir. The RMP details the important risks of Emtricitabine/Rilpivirine/Tenofovir, how these risks can be minimised, any uncertainties about Emtricitabine/Rilpivirine/Tenofovir (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for Emtricitabine/Rilpivirine/Tenofovir:

Important Identified Risks	• None
Important Potential Risks	• None
Missing Information	• Long-term safety information in adolescents • Safety in Pregnancy and Lactation

The company responsible for this product will collect further data to address the safety concern 'safety in pregnancy and lactation'. This data will be collected by participating in the Antiretroviral Pregnancy Registry. The purpose of the Antiretroviral Pregnancy Registry is to collect information on the risk of birth defects in patients exposed to emtricitabine/tenofovir alafenamide during pregnancy.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Emtricitabine/Rilpivirine/Tenofovir are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Other information about Emtricitabine/Rilpivirine/Tenofovir
A marketing authorisation was granted in the United Kingdom on 21 November 2025.

The full PAR for Emtricitabine/Rilpivirine/Tenofovir follows this summary.

This summary was last updated in January 2026.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Emtricitabine/Rilpivirine/Tenofovir Alafenamide 200 mg/25 mg/25 mg film-coated tablets (PL 04569/1886) could be approved.

Emtricitabine/Rilpivirine/Tenofovir Alafenamide is indicated for the treatment of adults and adolescents (aged 12 years and older with body weight at least 35 kg) infected with human immunodeficiency virus-1 (HIV-1) without known mutations associated with resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, tenofovir or emtricitabine and with a viral load ≤ 100 000 HIV-1 RNA copies/mL

For more information on the indications of this medicine, see the Summary of Product Characteristics available on the MHRA website.

The active substances in this product are emtricitabine, rilpivirine and tenofovir alafenamide.

Emtricitabine is a nucleoside reverse transcriptase inhibitor (NRTI) and analogue of 2'-deoxycytidine. Emtricitabine is phosphorylated by cellular enzymes to form emtricitabine triphosphate. Emtricitabine triphosphate competitively inhibits HIV-1 reverse transcriptase (RT), resulting in deoxyribonucleic acid (DNA) chain termination. Emtricitabine has activity against HIV-1, HIV-2, and HBV.

Rilpivirine is a diarylpyrimidine NNRTI of HIV-1. Rilpivirine activity is mediated by non-competitive inhibition of HIV-1 RT. Rilpivirine does not inhibit the human cellular DNA polymerases α, β and mitochondrial DNA polymerase γ.

Tenofovir alafenamide is a nucleotide reverse transcriptase inhibitor (NtRTI) and prodrug of tenofovir (2'-deoxyadenosine monophosphate analogue). Due to increased plasma stability and intracellular activation through hydrolysis by cathepsin A, tenofovir alafenamide is more efficient than tenofovir disoproxil fumarate in loading tenofovir into peripheral blood mononuclear cells (PBMCs) (including lymphocytes and other HIV target cells) and macrophages. Intracellular tenofovir is subsequently phosphorylated to the active metabolite tenofovir diphosphate. Tenofovir diphosphate inhibits HIV RT, resulting in DNA chain termination. Tenofovir has activity against HIV-1, HIV-2 and HBV.

This application was approved under International Recognition procedure (IRP). The Reference Regulator (RR) was the European Medicines Agency (EMA) , with the procedure number EMEA/H/C/006491. The procedure followed route A.

For the scientific discussion of the quality, non-clinical and clinical assessment conducted by the reference regulator, please refer to the public assessment report on the relevant competent authority's website.

This application was approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended).

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A marketing authorisation was granted on 21 November 2025.

II. PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with current guidelines and is satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

MHRA considered that the quality data submitted for this application are satisfactory. The grant of a) marketing authorisation was recommended.

IV. NON-CLINICAL ASPECTS

MHRA considered that the non-clinical data submitted for this application are satisfactory. The grant of a marketing authorisation was recommended.

V. CLINICAL ASPECTS

MHRA considered that the clinical data submitted for this application are satisfactory. The grant of a marketing authorisation was recommended.

VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. In addition to routine pharmacovigilance and risk minimisation measures, additional pharmacovigilance activities have been proposed (see table below for the risk minimisation measures and pharmacovigilance activities for all safety concerns):

Safety Concern	Risk Minimisation Measures	Pharmacovigilance Activities
Missing information: Long-term safety information in adolescents	Routine risk minimization measures: None Additional risk minimisation measures: None	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: None
Missing information: Safety in Pregnancy and Lactation	Routine risk minimization measures: SmPC section 4.6 PL section 2 Additional risk minimisation measures: None	Routine pharmacovigilance activities beyond adverse reaction reporting and signal detection: None Additional pharmacovigilance activities: Antiretroviral Pregnancy Registry (APR)

This is acceptable.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for this product are available on the MHRA website.

IX. TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**