



Monday 18th December 2023

University Hospitals Birmingham NHS Foundation Trust

Heartlands Hospital

Bordesley Green East

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Tel: 0121 424 2000

Steven.welch@uhb.nhs.uk

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Biktarvy[▼] 30 mg/120 mg/15 mg film-coated tablets (bictegravir 30mg/ emtricitabine 120mg/ tenofovir alafenamide 15mg):

Interim Supply of Ireland-Northern Ireland-Malta Stock to Mitigate Supply Disruption

Dear Dr Steven Welch

Summary: Gilead Sciences Ltd is currently experiencing supply disruption with Biktarvy 30 mg/120 mg/15 mg film-coated tablets (bictegravir 30mg/ emtricitabine 120mg/ tenofovir alafenamide 15mg) UK (Great Britain)

Biktarvy is indicated for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and paediatric patients at least 2 years of age and weighing at least 14 kg without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.

Posology for paediatric patients at least 2 years of age and weighing at least 14 kg to less than 25 kg is one Biktarvy 30 mg/120 mg/15 mg tablet to be taken once daily.

The Biktarvy 30 mg/120 mg/15 mg film-coated tablets you will be receiving is provided to you as Irish commercial branded stock in English language. A labelling exemption made under Regulation 266 of the Human Medicines Regulations 2012 was approved by the Medicines and Healthcare products Regulatory Agency (MHRA) on the 15th December 2023.

- This product is considered licensed in the UK (Great Britain)
- The product from Ireland has the same formulation as the UK (Great Britain) product
- The product from Ireland is manufactured according to the same manufacturing process and quality controls as the UK (Great Britain) product

Please find the Great Britain English language Summary of product Characteristics (SmPC) and Patient Information leaflet (PI) Biktarvy 30 mg/120 mg/15 mg film-coated tablets attached with this letter.

Electronic versions of the patient information leaflet can be found at:

- [Biktarvy 30 mg/120 mg/15 mg film-coated tablets - Patient Information Leaflet \(PIL\) - \(emc\) \(medicines.org.uk\)](https://www.medicines.org.uk)

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

Gilead Sciences Ltd
280 High Holborn, London, United Kingdom WC1V 7EE
Registered in England No 2543818

www.gilead.co.uk

UK-BVY- 1068 Date of preparation: December 2023



Call for reporting:

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the [Yellow Card website](#)
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystemOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

- Biktarvy ▼ is subject to additional monitoring. This will allow quick identification of new safety information
- Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle ▼ to the MHRA through the Yellow Card Scheme.

Suspected side effects can also be reported by calling 0800 731 6789 for free. Adverse events should also be reported to Gilead to safety_FC@gilead.com or +44 (0) 1223 897500.

Company contact point:

If you have any questions about this letter or require more information about Biktarvy, please contact Gilead Medical Information at ukmedinfo@gilead.com or telephone +44 (0)203 681 45000

Kind Regards

Chris Robinson

Gilead HIV Medical Director United Kingdom & Ireland

DocuSigned by:
Chris Robinson 12/18/2023
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