

Date: <XX Month YYYY>

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Harvoni 45 mg/200 mg film-coated tablets (ledipasvir/sofosbuvir):

Dear Healthcare Professional,

Summary: Gilead Sciences Ltd is currently experiencing supply disruption with Harvoni 45 mg/200 mg film-coated tablets (ledipasvir/sofosbuvir) in the UK.

Gilead Sciences Ltd has obtained approval from the MHRA to supply Irish product (batch number: MV0580AD; batch size: 50; number of packs: 14), which is expected to be on the UK market from today to 31st December 2020.

Please note the following:

- This product is considered licensed in the UK.
- The product from Ireland has the same formulation as the UK product.
- The product from Ireland is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are minor differences between the Irish and UK product information. Differences include the absence in the Patient Information Leaflet (PIL) of UK specific information on how to report suspected adverse reactions via the national reporting system as well as the absence on the outer packaging of UK specific blue box information.
- Please refer to the UK approved Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) supplied electronically with the Irish pack. Discard the Irish PIL in the pack.
- For additional copies of the leaflet, please refer to <https://www.medicines.org.uk/emc/> or contact the company contact point (see below).
- The MHRA has agreed to an exemption according to Article 63(3) of Council Directive 2001/83/EC, granted in accordance with regulation 266(4)(a) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Harvoni 45/200 mg film-coated tablets (ledipasvir/sofosbuvir).

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

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <https://www.gov.uk/yellowcard>, the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#), and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

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



GILEAD

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Company contact point

If you have any questions about this letter or wish more information about Harvoni, please contact Gilead Sciences Ltd Medical Information, 280 High Holborn, Holborn, London WC1V 7EE, or telephone +44 (0) 8000 113700 or ukmedinfo@gilead.com.