Date: 14th July 2026

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Stoboclo▼ 60mg/ml pre-filled syringe (Denosumab)
Interim supply of Irish Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Celltrion UK Ltd is currently experiencing supply disruption with Stoboclo▼ 60mg/ml pre-filled syringe (denosumab) in the UK (Great Britain).

To ensure continuity in supply, Celltrion UK Ltd has obtained approval from the MHRA to supply Irish product (batch number 5P1P09S31; (8000 packs) which is expected to be on the UK (Great Britain) market from July 2026 to December 2026.

Please note the following:

- This product is considered licensed in the UK.
- 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.
- There are no differences between the Irish and UK product information. Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) are followed.
- 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 granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Stoboclo and that the information must be given in English.

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

The only difference that occurs on the PIL and the Carton is the EU licence number and the contact details, however, should a patient or HCP contact Celltrion Hungary, Celltrion will ensure the communications are redirected accordingly.

Date of Preparation – July 2026.
Reference – UK-STB-26-00013.
Date of MHRA Approval – 14th July 2026.
This is a non-promotional letter intended for Healthcare Professionals in the UK Only.

The Charter Building, Charter Place, Uxbridge, UB8 1JG United Kingdom
VAT Number: GB 330 0102 86 / Company Registration number: 11685363

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/SystmOne/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.

Stoboclo▼ 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.

The non-identical nature of biological medicines and vaccines means it is very important that safety surveillance is carried out on a brand/product-specific basis. When reporting a suspected ADR to a biological medicine (such as blood products, antibodies and advanced therapies [such as gene and tissue therapy]) or vaccine, please ensure that you provide the brand name (or product licence number and manufacturer), and the specific batch-number.

Additionally, when providing patients with details of the vaccine or biological medicine administered, it is good practice to give them details of the brand and batch number. This will allow patients and carers to more accurately report suspected ADRs to the Yellow Card scheme.

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Company contact point
If you have any questions about this letter or require more information about Stoboclo, please contact Celltrion Healthcare UK limited at ukadverseevents@celltrionhc.com, or by calling +44(0)1753983500.

Yours faithfully,

Signé par :
DongSik Kim
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DongSik Kim,

Company Director (UK General Manger)

Celltrion Healthcare UK Limited.

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