HEALTHCARE CELLTRION

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IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Direct healthcare professional communication (DHPC)

Date: 16th February 2026

Remsima (infliximab): New IV formulation (100 mg and 350 mg concentrate for solution for infusion) contains sorbitol and is therefore contraindicated in patients with hereditary fructose intolerance

Dear Healthcare Professional,

The marketing authorisation holder, Celltrion Healthcare Hungary Kft. ("Celltrion"), in agreement with the European Medicines Agency (EMA) and the Health Products Regulatory Authority (HPRA), would like to inform you of the following:

Summary

Risk of serious metabolic harm in patients with hereditary fructose intolerance (HFI) due to sorbitol content of new IV Remsima formulation.

- **Remsima 100 mg and 350 mg concentrate for solution for infusion is a new intravenous (IV) formulation of infliximab; it contains 45mg of sorbitol per 1 mL.**
- **Intravenously administered medicines containing sorbitol are contraindicated in patients with HFI.**
- **In patients with HFI, even small amounts of intravenously administered sorbitol can result in severe adverse reactions, including hypoglycaemia, acute hepatic failure, haemorrhagic syndrome, renal failure, and death.**
- **The approved Remsima subcutaneous (SC) formulation also contains sorbitol, but is considered safe for patients with HFI due to the SC administration route.**
- **The previously available IV formulation of Remsima 100 mg powder for concentrate for solution for infusion does not contain sorbitol.**
- **Remsima 100 mg and 350 mg concentrate for solution for infusion is not freely interchangeable with other intravenous formulations of infliximab in patients with HFI.**

Background

Remsima (infliximab) is a biosimilar which has been authorised in the European Union (EU) since 10 September 2013. It is indicated for the treatment of rheumatoid arthritis, Crohn's disease (adult and paediatric), ulcerative colitis (adult and paediatric), ankylosing spondylitis, psoriatic arthritis and psoriasis.

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A new IV liquid formulation of Remsima has been authorised, which contains **sorbitol** as an excipient: Remsima 100 mg and 350 mg concentrate for solution for infusion. Intravenous medicines containing sorbitol are contraindicated in patients with hereditary fructose intolerance (HFI). Remsima 100 mg powder for concentrate for solution for infusion, which does not include sorbitol, will continue to be available for prescription for patient who might require it.

HFI is a rare hereditary autosomal recessive deficit in the main enzyme responsible for hepatic metabolism of fructose. The condition is normally diagnosed in infancy. Administration of sorbitol to patients with HFI may lead to intracellular accumulation of fructose 1-phosphate, which is highly toxic.

The product information and patient reminder card for Remsima have been updated to include the information that Remsima 100 mg and 350 mg concentrate for solution for infusion contains sorbitol and must not be given to patients with HFI.

Health care professionals must:

- confirm that the patient does not have HFI before administration of Remsima 100 mg or 350 mg concentrate for solution for infusion;
- be aware that Remsima 100 mg and 350 mg concentrate for solution for infusion is not freely interchangeable with other intravenous formulations of infliximab in patients with HFI;
- make sure that patients receive the updated patient card; and
- make HFI patients aware of the contraindication of the new formulation.

Please share this document with relevant members of your team.

Call for reporting

Healthcare professionals are asked to report any suspected adverse drug reactions in patients treated with Remsima (infliximab) 100mg and 350mg concentrate for solution for infusion, in accordance with the national spontaneous reporting system via HPRA Pharmacovigilance, website: www.hpra.ie. Please include batch/lot number if available.

Suspected adverse reactions should also be reported to Celltrion Healthcare Ireland Ltd by emailing medinfoie@celltrionhc.com or calling 01 564 5074.

Company contact point

For further information about this medicine, please contact Celltrion Healthcare Ireland at Enquiry_IE@celltrionhc.com or 01 223 4026.

Yours sincerely,

Signed by:
20BCB5BF5084450...

Dr David Woods
National Medical Lead
Celltrion Healthcare Ireland

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