sanofi

February 2023

Insuman[®] (human insulin) range discontinuation – Supply exhaustion update

Dear Healthcare Professional,

Following previous communication in January 2023 regarding discontinuation in the UK of Insuman[®] range, I am writing to update you in relation to expected supply exhaustion dates.

Unfortunately, due to unexpected capacity and component part constraints at plant, end of supply for the following two presentations is updated below:

- 1. Insuman[®] Basal 100 IU/ml suspension for injection in a cartridge (Insulin isophane human) Expected End of Supply: end of February 2023
- Insuman[®] Comb 25 100 IU/ml suspension for injection in a cartridge (Insulin biphasic isophane human)
 Expected End of Supply: end of February 2023

As it will not be an option to continue patients on treatment with these Insuman[®] presentation past this date, alternative treatment options should be considered for any remaining patients, under the supervision of their prescribing clinician.

The supply exhaustion dates of the other presentations of Insuman[®] currently being discontinued remain unchanged, as below:

- Insuman[®] Basal SoloStar 100 IU/ml suspension for injection in a pre-filled pen (Insulin isophane human)
 Expected End of Supply: June 2023
- Insuman[®] Comb 25 SoloStar 100 IU/ml suspension for injection in a pre-filled pen (Insulin biphasic isophane human)
 Expected End of Supply: June 2023
- 5. Insuman[®] Rapid 100 IU/ml solution for injection in a cartridge (Insulin soluble human) Expected End of Supply: May 2023

Expected end supply dates are only approximate and supply may be exhausted before/after these dates based on future patient demand.

Background:

Sanofi is committed to maintaining current supply of our analogue insulins to the UK and Ireland. We continuously reassess our product and device portfolio based on patient need, environmental changes and alternative therapies available. Demand for Insuman® regular human, isophane and isophane premixed insulins has declined significantly in recent years. The discontinuation of the human insulin range, Insuman® is part of our ongoing strategy to reduce manufacturing complexity by removing low-volume products where alternatives are available from other manufacturers. This process allows us to focus our effort and resource on improving capacity for remaining high-volume product lines, including analogue insulins.

Today, fewer than 1% of people receiving insulin in the UK are prescribed Insuman[®] regular human, isophane or isophane pre-mixed insulins, as people with diabetes are increasingly managed with modern analogue insulins. Furthermore, fewer than 3% of people prescribed a human insulin in the UK are prescribed Insuman[®] regular human, isophane or isophane pre-mixed insulins.¹

The decision has therefore been taken to discontinue the remaining presentations of Insuman[®] regular human, isophane and isophane pre-mixed insulins in the UK, phased over the next 6 months as outlined above.

Please note that no other Sanofi insulins are impacted by this decision.

Next steps:

If you have patients currently receiving treatment with any of the Insuman[®] presentations listed within, they should be moved to a suitable alternative treatment under the supervision of their prescribing clinician.

All the Insuman[®] presentations listed can continue to be used by your patients, prior to the dates outlined above, until they are able to transition to an alternative treatment.

Sanofi remains committed to people living with diabetes in the UK and their clinicians. We continue to act on this commitment through our medicines, services, technologies, and support for the wider community.

Human Insulins in the UK:

The following human insulin presentations are marketed in the UK²:

Manufacturer	Туре	Product
Eli Lilly and	Insulin soluble	Humulin S 100units/ml solution for injection 10ml vials
Company Ltd	human	
Novo Nordisk	Insulin soluble	Actrapid 100units/ml solution for injection 10ml vials
Ltd	human	
Eli Lilly and	Insulin soluble	Humulin S 100units/ml solution for injection 3ml cartridge
Company Ltd	human	
Eli Lilly and	Insulin isophane	Humulin I 100units/ml suspension for injection 10ml vials
Company Ltd	human	
Novo Nordisk	Insulin isophane	Insulatard 100units/ml suspension for injection 10ml vials
Ltd	human	
Eli Lilly and	Insulin isophane	Humulin I 100units/ml suspension for injection 3ml cartridges
Company Ltd	human	

Novo Nordisk	Insulin isophane	Insulatard Penfill 100units/ml suspension for injection 3ml
Ltd	human	cartridges
Eli Lilly and	Insulin isophane	Humulin I KwikPen 100units/ml suspension for injection 3ml
Company Ltd	human	pre-filled pens
Eli Lilly and	Insulin biphasic	Humulin M3 100units/ml suspension for injection 10ml vials
Company Ltd	isophane human	
Eli Lilly and	Insulin biphasic	Humulin M3 100units/ml suspension for injection 3ml
Company Ltd	isophane human	cartridges
Eli Lilly and	Insulin biphasic	Humulin M3 KwikPen 100units/ml suspension for injection 3ml
Company Ltd	isophane human	pre-filled pens

If you have any questions regarding this information or would like to speak to a member of our medical team, please contact our medical information department who can arrange that:

Medical Information at Sanofi, 410 Thames Valley Park Drive, Reading, RG6 1PT, UK

• Tel: +44 (0) 800 035 2525

Email: <u>uk-medicalinformation@sanofi.com</u>

- For questions relating to ordering, please contact:
 - Sanofi Customer Services Tel: +44 (0) 800 854 430 (Mon-Fri 9am 5pm).

Adverse events should be reported. Reporting forms and information can be found at <u>www.mhra.gov.uk/yellowcard</u> or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to the Sanofi drug safety department on Tel: 0800 0902 314. Alternatively, send via email to <u>UK@drugsafety@sanofi.com</u>

Sanofi apologies for any inconvenience that this discontinuation and stock exhaustion may cause you or your patients.

Yours Sincerely,

Ross Murphy Portfolio Strategy Manager, General Medicines Foundation UK & Ireland

References:

- 1. Longitudinal Patient Data, IQVIA Ltd, incorporating data derived from THIN, A Cegedim Database, (Data on file) Date accessed: Sept 2022
- 2. British National Formulary https://bnf.nice.org.uk/ accessed 14/12/2022

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