5th January 2017

Direct Healthcare Professional Communication announcing the end of the temporary supply shortage of certain presentations of INSUMAN® BASAL and INSUMAN® COMB 25 (insulin human)

Dear Healthcare Professional,

Summary

In November 2015 Sanofi wrote to you to highlight a lack of availability of certain presentations of Insuman® Basal and Insuman® Comb 25 (the active substance for both is insulin human). This was due to limited manufacturing capacity at the Sanofi manufacturing site.

Sanofi would now like to inform you of the resolution of these shortages in the United Kingdom.

The presentations concerned are:

- **Insuman® Basal** 100 IU/mL suspension for injection in a cartridge
- **Insuman® Comb 25** 100 IU/mL suspension for injection in a cartridge
- **Insuman® Basal Solostar®** 100 IU/mL suspension for injection in a pre-filled pen
- **Insuman® Comb 25 Solostar®** 100 IU/mL suspension for injection in a pre-filled pen

Normal production resumed in September 2016. Stocks in the different distribution centers, hospitals and pharmacies are currently being replenished and will be back to normal **by the end of March 2017**.

<u>Further information - implications for patients</u>

The re-conversion of patients initially treated with Insuman®, who were switched to an alternative insulin and who would like to come back to Insuman®, should be performed under the supervision of a Healthcare Professional and with close monitoring of blood glucose levels. Patients may need to be trained again in the use of the Insuman delivery device that is specific to each device manufacturer.

A letter on the end of the Insuman supply shortage is also being sent to patient organisations for people with diabetes and will be available on the eMC website [www.medicines.org.uk/] and the Sanofi website [www.sanofi.co.uk/].

This information has been approved for distribution by the Medicines and Healthcare products Regulatory Agency (MHRA).

Call for reporting

Please continue to report suspected adverse reactions (ADRs) with any medicine or vaccine to the MHRA through the Yellow Card Scheme online at www.mhra.gov.uk/yellowcard. 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 ▼

It is easiest and quickest to report ADRs online via the Yellow Cards website: www.mhra.gov.uk/yellowcard. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gsi.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- or by downloading and printing a form from the Yellow Card section of the MHRA website

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

Reports can also be made to the **Sanofi UK Pharmacovigilance** department at: Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS, UK. Tel: 01483 554242, Fax: 01483 554806, Email: uk-drugsafety@sanofi.com

Further information

Should you require additional information, please call **Medical Information** at Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS, UK - Tel: 0845 372 7101, Email: uk-medicalinformation@sanofi.com. For questions relating to product orders contact: Sanofi Customer Services – 0800 854 430, (9am – 5.15pm Monday-Thursday, 9am – 4pm Friday).

Yours faithfully,

Henrik Schou

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