



EMA/759044/2015 Rev.2

**Update of 17 November 2016:**

The shortage affecting Insuman Basal and Comb 25 (insulin human) has been resolved and the below information and recommendations which were issued during the shortage no longer apply.

13 July 2016

### Shortage of Insuman Basal and Comb 25 (insulin human) 3 ml cartridges and pre-filled pens

<b>Indication</b>	<p>Insuman is a range of insulin-containing solutions and suspensions for injection that are used in patients with diabetes (type 1 and 2) who need treatment with insulin.</p> <p>Insuman Basal is an intermediate-acting insulin suspension containing isophane insulin, and Insuman Comb is available in various combinations of fast- and intermediate-acting insulins.</p>
<b>Reason for shortage</b>	<p>In November 2015, limited manufacturing capacity at a Sanofi manufacturing site in Frankfurt, Germany, for Insuman prefilled pens and cartridges caused supply difficulties for some Insuman suspension presentations. A shortage therefore occurred which is expected to last until September 2016. This shortage follows a previous shortage that occurred earlier in 2015.</p>
<b>Member States affected</b>	<p>Germany, Hungary, Poland and the United Kingdom.</p>
<b>Information to healthcare professionals</b>	<ul style="list-style-type: none"><li>• Since December 2015, shortages of the following Insuman presentations are affecting some EU Member States: Insuman Basal and Comb 25 (prefilled pens and cartridges).</li><li>• Shortages are expected to last until September 2016.</li><li>• No new patients should be started on Insuman Basal and Comb 25 (prefilled pens and cartridges) during the shortage and existing patients should be switched to a suitable alternative. Healthcare professionals should preferably prescribe an alternative human insulin, taking into account local and national guidance. If switching to an insulin analogue, additional care should be taken, as dosing adjustments may be needed.</li><li>• Adequate training and support should be provided to patients who are being prescribed alternatives.</li><li>• Patients should be asked to monitor their blood glucose levels</li></ul>



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	<p>more frequently during the switch to alternative insulin.</p> <ul style="list-style-type: none"><li>• Healthcare professionals in countries affected have been informed in writing of the shortage.</li><li>• Additional advice may be available from the <a href="#">national competent authority</a>.</li></ul>
<b>Information to parents and carers</b>	<ul style="list-style-type: none"><li>• Since December 2015 a shortage of some types of Insuman products is affecting some EU countries. The products affected are: Insuman Basal and Comb 25 (prefilled pens and cartridges). The shortage may last until September 2016.</li><li>• During the shortage patients may be prescribed an alternative insulin medicine.</li><li>• Patients need to receive the necessary training on how to use the new insulin by their healthcare professional.</li><li>• When switched to a new insulin medicine, patients should monitor their blood sugar levels more frequently.</li><li>• Patients who have any questions should speak to their doctor or pharmacist.</li><li>• Additional advice may be available from the <a href="#">national competent authority</a>.</li></ul>