



19 January 2023
EMA/8885/2023 Rev.1¹

Shortage of Insuman Rapid, Basal and Comb 25 (insulin human) Solution for injection, prefilled pen

Indication	<p>Insuman is used in patients with diabetes (type 1 and 2) who need treatment with insulin.</p> <p>Insuman Rapid can also be used for the treatment of hyperglycaemic coma (coma caused by too much blood glucose [sugar]) and ketoacidosis (high levels of ketones [acids] in the blood), and to control blood glucose before, during or after an operation.</p>
Reason for shortage	<p>Several events at the manufacturing site resulted in a temporary supply shortage of Insuman in early 2023. They included supply delays of pen components and issues on filling, assembly and packaging lines. In addition, the marketing authorisation holder has decided to stop production and marketing of Insuman Rapid, Basal and Comb 25 worldwide.</p>
Member States affected²	<p>All EU Member States where Insuman Rapid, Basal and Comb 25 are currently authorised.</p>
Monitoring of shortage	<p>EMA's SPOC working party³ is closely monitoring the supply situation and engaging with the marketing authorisation holder and other stakeholders to identify measures to mitigate the impact of the supply shortage.</p>
Information to healthcare professionals	<ul style="list-style-type: none">• There have been supply shortages of Insuman Basal, Rapid and Comb 25 since January 2023. In addition, the marketing authorisation holder has decided to stop production and marketing of Insuman Rapid, Basal and Comb 25 worldwide.• As a result, no new patients should be started with any of the impacted Insuman products and existing patients

¹ This document was modified on 13 July 2023 to reflect the decision by the marketing authorisation holder to stop marketing the product and to reflect ongoing monitoring by the Medicine Shortages Single Point of Contact (SPOC) working party and additional measures to maintain supply.

² This information may change. For accurate information about the status of a medicine shortage in a particular Member State the national competent authority should be contacted.

³ The [SPOC working party](#) is responsible for monitoring and reporting events that could affect the supply of medicines in the EU. Summaries of the SPOC working party meetings can be found on [EMA's website](#).



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	<p>should be switched to suitable alternatives at the next scheduled appointment.</p> <ul style="list-style-type: none"> • Alternatives should be chosen based on national or local guidance and based on the patients' needs. The switch should be done under the supervision of a healthcare professional with close monitoring of blood glucose levels. • A delay in switching may result in patients missing the required doses, which may have serious clinical consequences such as hyperglycaemia. • A direct healthcare professional communication (DHPC) has been sent to relevant healthcare professionals and is also available on the EMA website. • Additional advice may be available from your country's national shortage register.
<p>Information to patients</p>	<ul style="list-style-type: none"> • There have been supply shortages of Insuman Basal, Rapid and Comb 25 since January 2023. In addition, the marketing authorisation holder has decided to stop production and marketing of Insuman Rapid, Basal and Comb 25 worldwide. If you take Insuman Basal, Rapid and Comb 25, make an appointment with your doctor before your current insulin supply finishes, so that a suitable alternative can be found. • A delay in switching may result in you missing doses, which may lead to high blood sugar levels. • Switching to an alternative medicine should be done under the supervision of a healthcare professional and with close monitoring of blood sugar levels. • If you have any questions, speak to your doctor or pharmacist. • Additional advice may be available from your country's national shortage register.
<p>Status</p>	<p>Ongoing</p>