



19 January 2023
EMA/8885/2023

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 have resulted in a temporary supply shortage of Insuman. They include supply delays of pen components and issues on filling, assembly and packaging lines.</p> <p>In addition, in a number of EU Member States, marketing of some presentations will cease.</p>
Member States affected¹	<p>Austria, Belgium, Bulgaria, Czechia, Denmark, Germany, Italy, Latvia, Netherlands, Norway, Poland, Portugal, Romania, Sweden.</p>
Information to healthcare professionals	<ul style="list-style-type: none">• Supply delays and technical issues at the manufacturing plant have led to supply shortages of Insuman Basal, Rapid and Comb 25. In addition, in a number of EU Member States, some presentations of the product will no longer be marketed.• As a result, no new patients should be started with any of the impacted Insuman products and existing patients should be switched to suitable alternatives at the next scheduled appointment.• Alternatives should be chosen based on national or local guidance and based on the patient's 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

¹ 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.



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	<p>the required doses, which may have serious clinical consequences such as hyperglycaemia.</p> <ul style="list-style-type: none"> • A direct healthcare professional communication (DHPC) has been sent to relevant healthcare professionals and is also available on the EMA website. • Additional advice, including information on suitable alternatives, may be available from the national competent authority.
<p>Information to patients</p>	<ul style="list-style-type: none"> • Supply delays and technical issues at the manufacturing plant have led to supply shortages of Insuman Basal, Rapid and Comb 25. In addition, in a number of EU Member States, some presentations of the product will no longer be marketed. • Your doctor will discuss with you the need to switch to an alternative medicine. Switching to an alternative medicine should be done under the supervision of a healthcare professional and with close monitoring of blood glucose levels. • 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. • If you have any questions, speak to your doctor or pharmacist. • Additional advice may be available from the national competent authority.
<p>Status</p>	<p>Ongoing</p>