



31 March 2015
EMA/182584/2015

Update of 15 September 2015: the shortage affecting Insuman has been resolved and the below information and recommendations which were issued during the shortage no longer apply.

Insuman Rapid, Basal and Comb(insulin human) 3 ml cartridges and pre-filled pens

Indication	<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>Some forms of Insuman can also be used for the treatment of hyperglycaemic coma (coma caused by very high blood glucose [sugar] levels) and ketoacidosis (high levels of certain substances [ketones] in the blood), and to control blood glucose before, during or after an operation.</p> <p>Insuman Rapid is a fast-acting insulin solution containing soluble insulin, 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>
Reason for shortage	<p>Following a problem in the manufacturing process of Insuman the marketing authorisation holder has reduced the production and release of all batches of Insuman Basal, Comb and Rapid (cartridges and pre-filled pens). While the issue is being addressed, a limited number of batches of Insuman cartridges and pre-filled pens will be produced or released and as a result a shortage may occur in some EU Member States by end of March 2015.</p>
Member States affected	<p>Temporary supply disruptions are expected to occur in the following EU Member States: Bulgaria, Czech Republic, Hungary, Norway and Poland.</p>
Information to healthcare professionals	<ul style="list-style-type: none">• Problems with the supply of Insuman cartridges (3 ml) and pre-filled pens (Rapid/Basal/Comb25) may affect some member states by the end of March.• The shortage does not affect Insuman vials. Insuman Implantable vials, Infusat vials and Infusat cartridges will also not be affected by the shortage.• In case of shortage, healthcare professionals should prescribe



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	<p>an alternative human insulin, taking into account local and national guidance.</p> <ul style="list-style-type: none">• Adequate training and support should be provided for patients who are being prescribed alternatives.• Patients should be asked to monitor their blood glucose levels closely during the switch to alternative human insulin.• Healthcare professionals in countries affected will be informed by the company of the shortage.• Additional advice may be available from the national competent authority.
Information to parents and carers	<ul style="list-style-type: none">• Problems with the supply of Insuman cartridges (3 ml cartridges and pre-filled pens (Rapid/Basal/Comb25) may affect some member states by the end of March.• The shortage does not affect Insuman vials. Insuman Implantable vials, Infusat vials and Infusat cartridges will also not be affected by the shortage.• During the shortage healthcare professionals may prescribe an alternative insulin medicine and provide the necessary training on how to use this medicine.• Patients should monitor their blood sugar levels more closely.• Patients who have any questions should speak to their doctor or pharmacist.• Additional advice may be available from the national competent authority.