

3 June 2024 EMA/120056/2024

Shortage of human normal immunoglobulins Solutions for injection or infusion	
What are human normal immunoglobulins used for?	Human normal immunoglobulins are highly purified proteins extracted from donated human blood. They contain mainly immunoglobulin G (IgG), a class of antibody with a wide range of activity against organisms that can cause infection.
	Human normal immunoglobulins are used to treat a range of diseases. These include primary immunodeficiency disorders (PID), secondary immunodeficiencies (SID) and immunomodulatory diseases.
Reason for shortage	There have been shortages of several medicines containing human normal immunoglobulins given by injection or infusion into a vein or under the skin. The causes of the shortages are multifactorial and include an unexpected increase in demand. These shortages affect medicines authorised across the EU/EEA as well as several medicines authorised at national level. They are expected to occur throughout 2024.
	The shortages are not related to a quality defect of the products or a safety issue.
Member States affected	The following countries are affected by the shortages: Austria, Belgium, Croatia, France, Hungary, Italy, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.
	This information may change. For up-to-date information about the status of a medicine shortage in a particular EU/EEA Member State, consult the <u>national</u> <u>shortage register</u> or contact the <u>national competent authority</u> .
Monitoring of shortage	EMA's <u>SPOC working party</u> is closely monitoring the supply situation and engaging with the marketing authorisation holders to identify measures to mitigate the impact of the supply shortage.
	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 <u>EMA's website</u> .

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Information to healthcare professionals	 In case of shortage, you should follow local and national guidance which may include prioritisation of indications or use of alternative treatment options. For additional information consult your country's <u>shortage register</u> or contact your <u>national competent authority</u> 	
Information to patients and carers	 If the human normal immunoglobulin medicine you are using is not available, your doctor will discuss suitable treatment alternatives with you, in line with the national guidance in your country. If you have any questions, speak to your doctor or pharmacist. For additional information, consult your country's <u>shortage register</u> or contact your <u>national competent authority</u> 	
Status	Ongoing	