

9 August 2023 EMA/335075/2023

Shortage of methotrexate Solution for injection, various strengths	
Indication	Methotrexate is used for two different groups of indications:
	• different types of cancer;
	 inflammatory diseases including rheumatoid arthritis, juvenile chronic arthritis, psoriasis and Crohn's disease.
Reason for shortage	There have been an unexpected increase in demand for methotrexate injections and delays in production which have led to supply shortages in some European countries.
Member States affected ¹	Austria, Belgium, Finland, France, Germany, Hungary, Italy, Luxembourg, Netherlands, Portugal and Romania.
Monitoring of shortage	EMA's <u>SPOC working party</u> ² is closely monitoring the supply situation and engaging with the marketing authorisation holders and other stakeholders to identify measures to mitigate the impact of the supply shortage.
Information to healthcare professionals	 Different manufacturing issues are affecting the supply of methotrexate injections in some European countries. Before starting treatment, healthcare professionals should ensure that sufficient supplies are available to complete the treatment (especially for the use in cancer). In case of supply shortages, healthcare professionals should consider alternative treatment options for their patients. Please consult your <u>national shortage register</u> for further advice, including advice on alternatives.

¹ This information may change. For accurate information about the status of a medicine shortage in a particular Member State, please consult the <u>national shortage register</u>. ² The SPOC working party is responsible for monitoring and reporting events that could affect the supply of

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 $^{^{2}}$ The <u>SPOC working party</u> 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 patients	 Different manufacturing issues are affecting the supply of methotrexate injections in some European countries. Your doctor will check that there are sufficient supplies available before starting treatment, especially if you are being treated for cancer. In case methotrexate injections become unavailable, your doctor will discuss possible alternatives with you. Please consult your <u>national shortage register</u> for further advice, including advice on alternatives.
Status	Ongoing