

04 June 2024 EMA/190060/2024

Shortage of salbutamol inhalation products Inhaler/nebuliser solution	
What are salbutamol inhalation products used for?	Salbutamol inhalation products are used to treat breathing problems in people with asthma, chronic obstructive lung disease (COPD) and similar conditions. They contain the active substance salbutamol, which works by relaxing the muscles of the airways in the lungs, making breathing easier.
	Salbutamol inhalation products are taken using an inhaler (which releases the medicine in puffs) or a nebuliser (which sprays a fine, liquid mist of medicine).
Reason for shortage	There has been an increase in demand for salbutamol inhalation products, which cannot be met by the current manufacturing capacity, combined with other manufacturing issues for some of the products. These issues have led to shortages of some salbutamol inhalation products in most European countries. The shortages are not related to a quality defect of the products or a safety issue.
Member States affected	The shortages may affect the following Member States: Austria, Belgium, Bulgaria, Cyprus, Czechia, Denmark, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.
	The shortage situation depends on the medicine and the Member State concerned. In some countries the shortages may be intermittent or already partially resolved with the measures taken at national level.
	Improvement in medicine supplies is expected by September 2024 in some countries but may last until the end of 2024 in others. For up-to-date information about the status of a medicine shortage in a particular EU/EEA Member State, consult the <u>national shortage register</u> or contact the <u>national competent authority</u> .
Monitoring of shortage	EMA's Medicine Shortages <u>SPOC</u> working party is closely monitoring the supply situation and engaging with the marketing authorisation holders to identify measures to mitigate the impact of the supply shortage. In particular, EMA is in close dialogue with companies to investigate whether the production can be increased to meet the demand.
	The SPOC working party is responsible for monitoring and reporting events that could affect the supply of medicines in the EU/EEA. Summaries of the SPOC working party meetings can be found on EMA's website .



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Information to healthcare professionals	 There are shortages of some salbutamol inhalation products in most EU/EEA countries. If the brand you dispense is not available, other salbutamol inhalation products or treatment alternatives may be available in your country. It is important not to over-order salbutamol to avoid worsening the situation. For additional information, consult your country's <u>shortage register</u> or contact your <u>national competent authority</u>.
Information to patients and carers	 There are shortages of some salbutamol inhalation products in several EU/EEA countries. If the brand you use is unavailable, there may be alternative salbutamol inhalation products authorised in your country, or treatment alternatives. Your doctor will discuss suitable options with you. You should order your medicine as normal; do not order additional supplies as this may put further strain on supplies. If you have any questions, speak to your doctor or pharmacist. You may also contact patient organisations such as the <u>European Federation of Allergy and Airways Diseases</u>, or national organisations. For additional information, consult your country's <u>shortage register</u> or contact your <u>national competent authority</u>
Status	Ongoing

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