



27 January 2023
EMA/27040/2023

Shortage of amoxicillin and amoxicillin/clavulanic acid Various presentations including paediatric formulations and presentations

Indication	Amoxicillin, alone or in combination with clavulanic acid, is an antibiotic used to treat a wide range of bacterial infections.
Reason for shortage	The shortage has several root causes, but the main one is a surge in respiratory infections that has led to an increase in demand for antibiotics. This is compounded by manufacturing delays and production capacity issues (lack of personnel). EMA has been closely monitoring the situation since November 2022 and has been engaging with key players in the supply chain of amoxicillin in order to agree possible mitigating measures, such as increasing manufacturing capacity. Based on current information from companies and stakeholders, it is expected that the situation will improve in the coming months.
Member States affected¹	Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Spain, Lithuania, Latvia, Luxembourg, Malta, Netherlands, Norway, Portugal, Poland, Romania, Slovenia, Slovakia and Sweden.
Information to healthcare professionals	<ul style="list-style-type: none">• A recent surge in respiratory infections has led to an increase in demand for antibiotics such as amoxicillin (alone and in combination with clavulanic acid), especially as paediatric formulations. In addition, manufacturing delays and production capacity issues have led to supply problems in the majority of the EU Member States.• Despite the ongoing shortages, alternative antibiotics are available. If amoxicillin is not available, an alternative antibiotic can be prescribed, based on national guidelines. Please check the current availability status of alternative medicinal products with your national competent authority.• As for all antibiotics, amoxicillin should only be prescribed to treat bacterial infections and not viral

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>infections such as cold and flu, where they are not effective.</p> <ul style="list-style-type: none"> • It is important not to over-order amoxicillin to prevent further aggravating the situation. • For further information on how this shortage is being handled at EU level please refer to the statement by EMA's MSSG 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"> • A recent surge in respiratory infections has led to an increase in demand for antibiotics such as amoxicillin (alone and in combination with clavulanic acid), especially as formulations for children. In addition, manufacturing delays and production capacity issues have led to supply problems in the majority of the EU Member States. • Your doctor will prescribe an alternative if amoxicillin is not available. For children, your pharmacist may make a preparation themselves. Ask your pharmacist for advice on how to give this to your child. • Your doctor will only prescribe amoxicillin to treat bacterial infections and not viral infections such as cold and flu, where antibiotics are not effective. • For further information on how this shortage is being handled at EU level please refer to the statement by EMA's MSSG available on the EMA website. • Patients who have any questions should speak to their doctor or pharmacist. • Additional advice may be available from the national competent authority.
<p>Status</p>	<p>Ongoing</p>