



27 January 2023
EMA/27040/2023 Rev.1¹

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	This shortage started in October 2022 and has several root causes, but the main reason was a surge in respiratory infections that led to an increased demand for antibiotics. This was compounded by manufacturing delays and production capacity issues (lack of personnel). EMA has closely monitored the situation and engaged with key players in the supply chain of amoxicillin in order to agree on possible mitigating measures, such as increasing manufacturing capacity. Following these actions, the situation has already improved in many EU Member States.
Member States affected²	Austria, Belgium, Bulgaria, Croatia, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Spain, Lithuania, Latvia, Luxembourg, Malta, Netherlands, Portugal, Romania and Slovenia.
Monitoring of shortage	EMA, together with the European Commission's Directorate General for Health Emergency Preparedness and Response (DG HERA), is monitoring the supply and demand of a subset of antibiotics, including amoxicillin, to speed up measures to avoid new shortages during the next winter season.
Information to healthcare professionals	<ul style="list-style-type: none">A surge in respiratory infections during the winter of 2022/2023 led to an increase in the 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 led to supply problems in the majority of the EU Member States.

¹ This document was modified on 17 July 2023 to update the list of Member States affected and to reflect ongoing monitoring by EMA and DG HERA.

² 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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	<ul style="list-style-type: none"> • Although the situation has improved in recent months, shortages are still ongoing in some countries. Where shortages are ongoing, 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 infections such as cold and flu, where they are not effective. • It is important not to over-order amoxicillin to prevent shortages. • Please consult your national shortage register for further advice.
<p>Information to patients</p>	<ul style="list-style-type: none"> • A surge in respiratory infections during the winter of 2022/2023 led to an increase in the 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 led to supply problems in the majority of the EU Member States. • Although the situation has improved in recent months, shortages are still ongoing in some countries. Where shortages are ongoing, 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 preparation 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. • If you have any questions you should speak to your doctor or pharmacist. • Please consult your national shortage register for further advice, including advice on alternatives.
<p>Status</p>	<p>Ongoing</p>