



10 May 2023
EMA/178228/2023 Rev.1¹

Shortage of Abraxane (paclitaxel) paclitaxel formulated as albumin-bound nanoparticles / 5 mg/ml powder for dispersion for infusion	
Indication	<p>Abraxane is used to treat:</p> <ul style="list-style-type: none">• metastatic breast cancer, when the first treatment has stopped working and standard treatment including an anthracycline is not suitable;• metastatic adenocarcinoma of the pancreas, as a first treatment in combination with another cancer medicine, gemcitabine;• non-small cell lung cancer, as a first treatment in combination with the cancer medicine carboplatin when the patient cannot have surgery or radiotherapy.
Reason for shortage	<p>There has been an increase in demand in Europe for albumin-bound nanoparticle paclitaxel, which has led to low stocks of Abraxane.</p> <p>Despite measures to address manufacturing capacity, supply of Abraxane is limited and intermittent supply shortages may therefore occur in Greece and Italy; these potential shortages are expected to last until December 2023.</p> <p>The shortage is not related to a quality defect of the product or a safety issue.</p>
Member States affected²	Greece and Italy.
Monitoring of shortage	EMA's SPOC working party ³ is closely monitoring the supply situation and engaging with the marketing authorisation holder and other stakeholders to identify measures to mitigate the impact of the supply shortage (including the measures below).

¹ This document was modified on 29 August 2023 to update information on the shortage of Abraxane and to reflect ongoing monitoring by the Medicines Shortages Single Point of Contact (SPOC) working party and additional measures to maintain supply.

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.

³ The SPOC working party is responsible for monitoring and reporting events that could affect the supply of medicines in the EU.



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<p>Information to healthcare professionals</p>	<ul style="list-style-type: none"> • An increase in demand for albumin-bound nanoparticle paclitaxel has led to low stocks of Abraxane. Despite measures to address manufacturing capacity, intermittent supply shortages of the medicine may occur and are expected to last until December 2023. • The company that markets Abraxane is working with national authorities to assess how to allocate global stocks across EU Member States. • In the meantime, healthcare professionals should consider alternative treatment options for their patients if Abraxane is not available. • Additional advice, including information on suitable alternatives, may be available from your national shortage register or national competent authority.
<p>Information to patients</p>	<ul style="list-style-type: none"> • Abraxane contains the cancer medicine paclitaxel attached to the human protein albumin, in the form of tiny particles known as nanoparticles. • An increase in demand for albumin-bound nanoparticle paclitaxel may lead to intermittent supply shortages of Abraxane may occur in some EU countries. • Your doctor will prescribe you a treatment alternative if Abraxane is not available. • If you have any questions, speak to your doctor or pharmacist. • Additional advice may be available from your national shortage register or national competent authority.
<p>Status</p>	<p>Ongoing; expected to last until December 2023.</p>