EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 November 2023
EMA/20760/2023 Rev.2[1]

Shortage of Pazenir (paclitaxel)
paclitaxel formulated as albumin-bound nanoparticles / 5 mg/ml powder for dispersion for infusion

Indication	Pazenir is used to treat: • 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	There has been an increase in demand in Europe for albumin-bound nanoparticle paclitaxel throughout 2023, which has led to a limited supply or shortage of Pazenir in most EU Member States where it is marketed. The company that markets Pazenir has since made the commercial decision to stop marketing the medicine in the majority of EU Member States in order to redistribute supplies to countries outside the EU. This will last at least until the end of 2024. Member States affected by the decision will be notified by the company of the expected start date of the market withdrawal.
Member States affected[2]	Austria, Bulgaria, Croatia, Czechia, Estonia, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Portugal, Romania, Slovakia, Slovenia and Spain.

[1] This document was first published on 24 January 2023. It was modified on 27 June 2023 to update information on the shortage of Pazenir and to reflect ongoing monitoring by the Medicines Shortages Single Point of Contact (SPOC) working party and additional measures to maintain supply. It was further modified on 21 November 2023 to reflect the company's decision to stop marketing Pazenir in the majority of EU Member States.
[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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Monitoring of shortage	EMA's SPOC working party[3] is aware of the impact of this commercial decision on patients and is closely monitoring the supply situation. Commercial decisions are made independently of EMA. The working party is liaising with the marketing authorisation holder and also engaging with other stakeholders to identify measures to mitigate the impact of the supply shortage. Summaries of the SPOC working party meetings can be found on EMA's website.
Information for healthcare professionals	• There has been an increase in demand in Europe for albumin-bound nanoparticle paclitaxel throughout 2023, which has led to a shortage of Pazenir. • The company that markets Pazenir has since made the commercial decision to stop marketing the medicine in the majority of EU Member States so that supplies can be redistributed to countries outside the EU. This is expected to last at least until the end of 2024. • Pazenir will still be available in France, Germany and Sweden throughout 2024. • Healthcare professionals should consider alternative treatment options for their existing patients if Pazenir is not available in their country. • Pazenir treatment should not be started for new patients. • A direct healthcare professional communication (DHPC) on the Pazenir shortage was previously sent to healthcare professionals in affected Member States and is also available on the EMA website. • Additional advice, including information on suitable alternatives, may be available from your national shortage register or national competent authority.
Information for patients	• Pazenir contains the cancer medicine paclitaxel attached to the human protein albumin, in the form of tiny particles known as nanoparticles (albumin-bound nanoparticle paclitaxel). • There has been an increase in demand in Europe for albumin-bound nanoparticle paclitaxel, which has led to a shortage of Pazenir in some EU countries. • The company that markets Pazenir has since decided to stop marketing the medicine in most EU Member

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

	States and redistribute supplies to countries outside the EU. This will last at least until 2024. • Your doctor will prescribe you a treatment alternative if Pazenir 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.
Status	Ongoing