

April 2026

Enzalutamide Astellas 40mg film-coated tablet: enzalutamide laboratory test interference leading to falsely elevated digoxin plasma levels

Dear Healthcare Professional,

Astellas Pharma Ltd. in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- **Falsely elevated digoxin plasma level results with the chemiluminescent microparticle immunoassay (CMIA) have been identified in patients treated with enzalutamide, independently of being treated with digoxin**
- **Therefore, results of digoxin plasma levels obtained by CMIA should be interpreted with caution in patients taking enzalutamide and confirmed by another type of assay such as liquid chromatography-tandem mass spectrometry (LC-MS/MS) before taking any action regarding digoxin dose adjustment or discontinuation**
- **Laboratories should consider adding an advisory comment to serum digoxin level reports**
- **Healthcare professionals should consider the need to carry out a review of previously reported test results**

Background on the safety concern

Enzalutamide is an androgen receptor inhibitor indicated for prostate cancer. Digoxin is a cardiac glycoside used as an inotrope to improve systolic dysfunction in patients with congestive heart failure, and in the management of certain supraventricular arrhythmias, particularly chronic atrial flutter and fibrillation.

Based on a review of the available information from the individual case safety reports sourced from safety databases, along with a review of scientific literature, it has been concluded that enzalutamide may interfere with the CMIA laboratory test method, leading to falsely elevated digoxin plasma level results in patients taking enzalutamide, regardless of whether the patient is taking digoxin or not. In case of doubtful results, it is recommended that

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confirmation of serum digoxin levels is obtained by another type of assay without known interference before determining the need for any discontinuation of or decrease in dose of digoxin in patients taking enzalutamide.

The Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) has recommended that the laboratory test interference by enzalutamide leading to falsely elevated digoxin levels should be reflected in the product information for both enzalutamide and digoxin products. MHRA agrees with this recommendation.

Recommendation for sharing

This communication should be shared with relevant colleagues to ensure that healthcare professionals are informed of this safety information.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website on <https://yellowcard.mhra.gov.uk/>
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting, please provide as much information as possible, including



information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contact point

Should you have any questions regarding the contents of this letter or the use of Enzalutamide Astellas 40mg film-coated tablets, please contact:

Astellas Drug Safety

Tel: +44 (0)800 783 5018

Email: pharmacovigilance.gb@astellas.com

Or

Email: medinfo.est-m@astellas.com

Dr T Patel

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Reason: I agree to the terms defined by the placement of my signature on this document.

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Medical Director, UK

Astellas Pharma Ltd.

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