30 June 2025[1]
EMA/PRAC/179173/2025
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 2-5 June 2025 PRAC

The product information wording in this document is extracted from the document entitled 'PRAC recommendations on signals' which contains the whole text of the PRAC recommendations for product information update, as well as some general guidance on the handling of signals. It can be found on the webpage for PRAC recommendations on safety signals (in English only).

New text to be added to the product information is underlined. Current text to be deleted is ~~struck through~~.

1. Ciltabtagene autoleucel – Immune-mediated enterocolitis/ immune effector cell-associated enteritis with CAR T-cell products (EPITT no 20133)

Summary of product characteristics

4.4 Special warnings and precautions for use

Immune-mediated enterocolitis

Patients may develop immune-mediated enterocolitis, which may emerge several months after Carvykti infusion. Some cases may be refractory to treatment with corticosteroids, and other treatment options may be relevant to consider. There were events of gastrointestinal perforation, including fatal outcomes.

4.8 Undesirable effects

Table 4: Adverse reactions in patients with multiple myeloma treated with CARVYKTI

Gastrointestinal disorders

[1] Expected publication date. The actual publication date can be checked on the webpage dedicated to PRAC recommendations on safety signals.

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Immune-mediated enterocolitis, frequency "Common"

Package leaflet

4. Possible side effects

Other side effects

Common (may affect up to 1 in 10 people)

- Gastroenteritis, immune-mediated enterocolitis (inflamed stomach and gut)

2. Brodalumab – Pyoderma gangrenosum (EPITT no 20162)

Summary of product characteristics

4.8 Undesirable effects

Skin and subcutaneous tissue disorders

Frequency: Not known

Pyoderma gangrenosum

Package leaflet

4. Possible side effects

Other side effects

Not known (frequency cannot be estimated from the available data)

- Painful swelling and skin ulceration (pyoderma gangrenosum)

3. Enzalutamide; digoxin – Laboratory test interference leading to falsely elevated digoxin plasma levels with enzalutamide (EPITT no 20134)

Enzalutamide

Summary of product characteristics

4.5 Interaction with other medicinal products and other forms of interaction

P-gp substrates

[…] The plasma levels of digoxin were measured using a validated liquid chromatography-tandem mass spectrometry assay. […]

Laboratory Test Interference

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 and confirmed by another type of assay before taking any action with digoxin doses.

Digoxin

Summary of product characteristics

4.4 Special warnings and precautions for use

Laboratory Test Interference

Falsely elevated serum levels of digoxin may occur when samples from patients receiving enzalutamide are analysed using the chemiluminescent microparticle immunoassay (CMIA), independently of being treated with digoxin. In case of doubtful results, it is recommended to confirm digoxin serum levels with an alternative assay without known interference, in order to avoid any unnecessary discontinuation or decrease in the dose of digoxin (see section 4.5).

4.5 Interaction with other medicinal products and other forms of interaction

Determination of serum digoxin concentrations with the chemiluminescent microparticle immunoassay (CMIA) while using enzalutamide may cause falsely elevated serum digoxin levels. Results should be confirmed by another type of assay (see section 4.4).

Package leaflet

2. What you need to know before you take <product name>

Other medicines and <product name>

Tell your doctor if you take a medicine containing enzalutamide (for the treatment of prostate cancer). It may interfere with your digoxin tests.

4. Vortioxetine – Hallucinations, not related to serotoninergic syndrome (EPITT no 20152)

Summary of product characteristics

4.8 Undesirable effects

Psychiatric disorders

Hallucinations, frequency "Uncommon"

Package leaflet

4. Possible side effects

Uncommon: may affect up to 1 in 100 people

Hallucinations (seeing, hearing or feeling things that are not there)