



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 February 2020¹
EMA/PRAC/8638/2020
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 13-16 January 2020 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 [here](#) (in English only).

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

1. Abiraterone – Interaction with sulphonylureas leading to hypoglycaemia (EPITT no 19445)

Summary of product characteristics

4.4. Special warnings and precautions for use

Hyperglycaemia

The use of glucocorticoids could increase hyperglycaemia, therefore blood sugar should be measured frequently in patients with diabetes.

Hypoglycaemia

Cases of hypoglycaemia have been reported when ZYTIGA was administered to patients with pre-existing diabetes receiving pioglitazone or repaglinide (see section 4.5); therefore, blood sugar should be measured frequently in patients with diabetes.

4.5. Interaction with other medicinal products and other forms of interaction

Interactions with other medicinal products

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



Potential to affect exposures to other medicinal products

[...]

In a CYP2C8 drug-drug interaction trial in healthy subjects, the AUC of pioglitazone was increased by 46% and the AUCs for M-III and M-IV, the active metabolites of pioglitazone, each decreased by 10% when pioglitazone was given together with a single dose of 1,000 mg abiraterone acetate. ~~Although these results indicate that no clinically meaningful increases in exposure are expected when ZYTIGA is combined with medicinal products that are predominantly eliminated by CYP2C8.~~ Patients should be monitored for signs of toxicity related to a CYP2C8 substrate with a narrow therapeutic index if used concomitantly. Examples of medicinal products metabolised by CYP2C8 include pioglitazone and repaglinide (see section 4.4).

Package leaflet

2. What you need to know before you take Zytiga

Other medicines and ZYTIGA

Ask your doctor or pharmacist for advice before taking any medicine.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is important because ZYTIGA may increase the effects of a number of medicines including heart medicines, tranquilisers, some medicines for diabetes, herbal medicines (e.g., St John's wort) and others. [...]

2. Golimumab – Inflammatory myopathy (EPITT no 19460)

Summary of product characteristics

4.8. Undesirable effects

Tabulated list of adverse reactions

Skin and subcutaneous tissue disorders

Not known: Worsening of symptoms of dermatomyositis

Package leaflet

4. Possible side effects

The following additional side effects have been observed with Simponi:

Side effects of which the frequency is not known:

Worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness)