



3 July 2023¹
EMA/PRAC/248310/2023
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 5-8 June 2023 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. Nivolumab – Cytokine release syndrome (EPITT no 19880)

Summary of product characteristics

4.8. Undesirable effects

Table 6: Adverse reactions with nivolumab monotherapy

	Nivolumab monotherapy
Immune system disorders	
Common	infusion related reaction (<u>including cytokine release syndrome</u>), hypersensitivity (including anaphylactic reaction)

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



Table 7: Adverse reactions with nivolumab in combination with other therapeutic agents

	Combination with ipilimumab (with or without chemotherapy)	Combination with chemotherapy	Combination with cabozantinib
Immune system disorders			
Common	infusion related reaction (including cytokine release syndrome), hypersensitivity	infusion related reaction (including cytokine release syndrome), hypersensitivity	hypersensitivity (including anaphylactic reaction)
Uncommon			infusion related hypersensitivity reaction

2. Tofacitinib – Acnes (EPITT no 19885)

Summary of product characteristics

4.8. Undesirable effects

Skin and subcutaneous tissue disorders

Frequency 'common': Acne

Package leaflet

4. Possible side effects

Common (may affect up to 1 in 10 people): Acne