28 October 2019[1]
EMA/PRAC/532016/2019
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 30 September-3 October 2019 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. Durvalumab – Myasthenia gravis (EPITT no 19451)

Summary of product characteristics

4.2. Posology and method of administration

Adverse reactions	**Severity** [a]	**IMFINZI treatment modification**	**Corticosteroid treatment unless otherwise specified**
Other immune-mediated adverse reactions	Grade 3	Withhold dose	Consider initial dose of 1 mg/kg/day to 4 mg/kg/day prednisone or equivalent followed by taper
	Grade 4	Permanently discontinue [d]	

d) For myasthenia gravis, if there are signs of muscular weakness or respiratory insufficiency, IMFINZI should be permanently discontinued.

4.4. Special warnings and precautions for use

Other immune-mediated adverse reactions

Given the mechanism of action of IMFINZI, other potential immune-mediated adverse reactions may occur. The following immune-related adverse reactions were reported in less than 1% of patients

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

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treated with IMFINZI monotherapy in clinical trials (n = 1889): myasthenia gravis, myocarditis, myositis, polymyositis. Patients should be monitored for signs and symptoms and managed as recommended in section 4.2.

4.8. Undesirable effects

Nervous system disorders

Rare: Myasthenia gravis

Package leaflet

2. Warnings and precautions

Your doctor may delay the next dose of IMFINZI or stop your treatment with IMFINZI, if you have:

- Inflammation or problems of the muscles: symptoms may include muscle pain, or weakness or rapid fatigue of the muscles;

4. Possible side effects
Rare: a condition in which the muscles become weak and there is a rapid fatigue of the muscles (myasthenia gravis).

2. Lithium – Drug-induced lichenoid reaction (EPITT no 19389)

Summary of product characteristics

4.8. Undesirable effects

Tabulated list of adverse reactions

Skin and subcutaneous tissue disorders

Frequency not known: lichenoid drug reaction

Package leaflet

4. Possible side effects

Frequency not known: eruption of the skin or mucous membranes (lichenoid drug reaction)