



21 November 2022<sup>1</sup>  
EMA/PRAC/845794/2022  
Pharmacovigilance Risk Assessment Committee (PRAC)

## New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 24-27 October 2022 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 – Myelitis transverse (EPITT no 19815)

#### Summary of product characteristics

##### 4.2 Posology and method of administration

<b>Adverse reactions</b>	<b>Severity<sup>a</sup></b>	<b>IMFINZI treatment modification</b>	<b>Corticosteroid treatment unless otherwise specified</b>
<u>Immune-mediated myelitis transverse</u>	<u>Any grade</u>	<u>Permanently discontinue</u>	<u>Initiate 1 to 2 mg/kg/day prednisone or equivalent followed by taper</u>

##### 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 have been observed in patients treated with IMFINZI monotherapy: myasthenia gravis, myelitis transverse, myositis, polymyositis, meningitis, encephalitis, Guillain-Barré syndrome, immune thrombocytopenia, cystitis noninfective and pancreatitis (see section 4.8). [...]

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



#### 4.8. Undesirable effects

Table 3. Adverse drug reactions in patients treated with IMFINZI monotherapy and IMFINZI in combination with chemotherapy

	IMFINZI Monotherapy		IMFINZI Combined with Chemotherapy	
	Any Grade (%)	Grade 3-4 (%)	Any Grade (%)	Grade 3-4 (%)
<b>Nervous System Disorders</b>				
[...]	[...]			
<u>Myelitis transverse</u>	<u>Not known<sup>bb</sup></u>			

<sup>bb</sup> events were reported from post-marketing data

#### 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;
- inflammation of the spinal cord (transverse myelitis): symptoms may include pain, numbness, tingling, or weakness in the arms or legs; bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation.

## 2. Elasomeran (COVID-19 mRNA vaccine - Spikevax) – Heavy menstrual bleeding (EPITT no 19780)

#### Summary of product characteristics

##### 4.8 Undesirable effects

##### Reproductive system and breast disorders

[Frequency] Not known: Heavy menstrual bleeding\*

[Under table] \* Most cases appeared to be non-serious and temporary in nature.

#### Package leaflet

##### 4. Possible side effects

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

Heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

### **3. Tozinameran (COVID-19 mRNA vaccine - Comirnaty) – Heavy menstrual bleeding (EPITT no 19783)**

#### **Summary of product characteristics**

#### 4.8 Undesirable effects

##### Reproductive system and breast disorders

[Frequency] Not known: Heavy menstrual bleeding\*

[Under table] \* Most cases appeared to be non-serious and temporary in nature.

#### **Package leaflet**

#### 4. Possible side effects

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

Heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)