



7 February 2022¹
EMA/PRAC/13256/2022
Pharmacovigilance Risk Assessment Committee (PRAC)

New product information wording – Extracts from PRAC recommendations on signals

Adopted at the 10-13 January 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 – Arthralgia (EPITT no 19709)

Summary of product characteristics

4.8. Undesirable effects

	IMFINZI Monotherapy			IMFINZI Combined with Chemotherapy		
	Any Grade (%)	Grade 3-4 (%)	Grade 3-4 (%)	Any Grade (%)	Grade 3-4 (%)	Grade 3-4 (%)
Musculoskeletal and connective tissue disorders						
<u>Arthralgia</u>	<u>Very common</u>	<u>10.3</u>	<u>0.3</u>	<u>Common</u>	<u>2.6</u>	<u>0.4</u>

Package leaflet

4. Possible side effects

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



Very common (may affect more than 1 in 10 people)

- [...]
- joint pain (arthralgia)

2. Pregabalin – Toxic epidermal necrolysis (EPITT no 19723)

Summary of product characteristics

4.4. Special warnings and precautions for use

Severe cutaneous adverse reactions (SCARs) including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), which can be life-threatening or fatal, have been reported rarely in association with pregabalin treatment. At the time of prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, pregabalin should be withdrawn immediately and an alternative treatment considered (as appropriate).

4.8. Undesirable effects

The following adverse reaction should be added under the SOC Skin and subcutaneous tissue disorders:

Frequency 'rare': Toxic Epidermal Necrolysis

Package leaflet

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

Serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis have been reported in association with pregabalin. Stop using pregabalin and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

4. Possible side effects

Frequency 'rare':

Allergic reactions (which may include difficulty breathing, inflammation of the eyes (keratitis) and a serious skin reaction characterized by ~~rash, blisters, peeling skin and pain~~); reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).

[...]

If you experience swollen face or tongue or if your skin turns red and starts to blister or peel, you should seek immediate medical advice.