



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

26 September 2022<sup>1</sup>  
EMA/PRAC/699722/2022  
Pharmacovigilance Risk Assessment Committee (PRAC)

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

Adopted at the 29 August – 1 September 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. Pneumococcal polysaccharide vaccine (23 serotypes) – Extensive swelling of vaccinated limb (EPITT no 19768)**

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

##### 4.8. Undesirable effects

##### b. Tabulated list of adverse reactions

[...]

General disorders and administration site conditions

[...]

Frequency rare:

~~Injection-site cellulitis~~ Extensive swelling of the vaccinated limb†

[...]

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



† with short onset time from vaccine administration; defined by clinical review of cases reporting the preferred terms of extensive swelling of the vaccinated limb, injection site cellulitis and cellulitis, all of which described cellulitis-like reactions.

### **Package leaflet**

#### 4. Possible side effects

[...]

Side effects

[...]

Other side effects include:

Rare (may affect up to 1 in 1,000 people):

extensive swelling in of the injected vaccinated limb.