



27 September 2021<sup>1</sup>  
EMA/PRAC/468916/2021  
Pharmacovigilance Risk Assessment Committee (PRAC)

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

Adopted at the 30 August-2 September 2021 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. Methotrexate – Progressive multifocal leukoencephalopathy (EPITT no 18473)

#### Summary of product characteristics

##### 4.4. Special warnings and precautions for use

##### Progressive multifocal leukoencephalopathy (PML)

Cases of progressive multifocal leukoencephalopathy (PML) have been reported in patients receiving methotrexate, mostly in combination with other immunosuppressive medication. PML can be fatal and should be considered in the differential diagnosis in immunosuppressed patients with new onset or worsening neurological symptoms.

#### Package leaflet

##### 2. What you need to know before you take Methotrexate

If you, your partner or your caregiver notice new onset or worsening of neurological symptoms including general muscle weakness, disturbance of vision, changes in thinking, memory and orientation leading to confusion and personality changes contact your doctor immediately because these may be

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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](#).



symptoms of a very rare, serious brain infection called progressive multifocal leukoencephalopathy (PML).

## **2. Ponatinib – Panniculitis (EPITT no 19681)**

### **Summary of product characteristics**

#### 4.8. Undesirable effects

Table 4

Skin and subcutaneous tissue disorders

Rare: panniculitis (including erythema nodosum)

### **Package leaflet**

#### 4. Possible side effects

Other possible side effects that may occur with the following frequencies are:

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

- Painful red lumps, skin pain, skin reddening (inflammation of fatty tissue under the skin)