



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

6 March 2023<sup>1</sup>  
EMA/PRAC/57498/2023  
Pharmacovigilance Risk Assessment Committee (PRAC)

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

Adopted at the 6-9 February 2023 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. Bosutinib – Interstitial lung disease (EPITT no 19843)

#### Summary of product characteristics

##### 4.8. Undesirable effects

Respiratory, thoracic and mediastinal disorders

Frequency 'not known': Interstitial lung disease

#### Package leaflet

##### 4. Possible side effects

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

Interstitial lung disease (disorders causing scarring in the lungs): signs include cough, difficulty breathing, painful breathing.

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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](#).



## 2. Colistimethate sodium for intravenous use – Pseudo-Bartter syndrome (EPITT no 19845)

### Summary of product characteristics (SmPC)

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

Few cases of pseudo-Bartter syndrome have been reported in children and adults with the intravenous use of colistimethate sodium. Monitoring of serum electrolytes should be started in suspected cases and appropriate management should be implemented, however, normalisation of electrolyte imbalance might not be achieved without discontinuation of colistimethate sodium.

#### 4.8. Undesirable effects

<for SmPCs with a tabulated summary of adverse reactions:>

Metabolism and nutrition disorders: frequency “not known” - Pseudo-Bartter syndrome <as a footnote> See section 4.4.

<for SmPCs without a tabulated summary of adverse reactions:>

Pseudo-Bartter syndrome has been reported after intravenous administration of colistimethate sodium with unknown frequency (see section 4.4).

### Package leaflet

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

##### Warning and Precautions

If you experience muscle spasm, fatigue or increased urine output at any time, tell your doctor immediately as these events may be related to a condition known as pseudo-Bartter syndrome.

#### 4. Possible side effects

You may experience, after intravenous administration, the following symptoms that may be related to a condition known as pseudo-Bartter syndrome (see section 2):

- muscle spasm
- increase in urine output
- fatigue