



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 September 2017  
EMA/PRAC/406998/2017 Corr<sup>1</sup>  
Pharmacovigilance Risk Assessment Committee (PRAC)

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

Adopted at the 29 August-1 September 2017 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. Mesalazine – Risk of photosensitivity reactions (EPITT no 18869)

#### Summary of product characteristics

##### 4.8. Undesirable effects

Skin and subcutaneous tissue disorders

Frequency 'rare': Photosensitivity\*

\*see section c)

#### Photosensitivity

More severe reactions are reported in patients with pre-existing skin conditions such as atopic dermatitis and atopic eczema.

#### Package leaflet

##### 4. Possible side effects

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<sup>1</sup> Please see page 2 for corrections implemented on 6 October 2017 in the pramipexole package leaflet.



Rare side effects

- Increased sensitivity of your skin to sun and ultraviolet light (photosensitivity).

## 2. Pramipexole – Dystonia (EPITT no 18866)

### Summary of product characteristics

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

Dyskinesia

[...]

#### Dystonia

Axial dystonia including antecollis, camptocormia and pleurothotonus (Pisa Syndrome) has occasionally been reported in patients with Parkinson's disease following initiation or incremental dose increase of pramipexole. Although dystonia may be a symptom of Parkinson's disease, the symptoms in these patients have improved after reduction or withdrawal of pramipexole. If dystonia occurs, the dopaminergic medication regimen should be reviewed and an adjustment in the dose of pramipexole considered.

### Package leaflet

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

##### Warnings and precautions

Talk to your doctor before taking <product name>. Tell your doctor if you have (had) or develop any medical conditions or symptoms, especially any of the following:

[...]

- Dyskinesia

[...]

- Dystonia<sup>2</sup> (inability of keeping your body and neck straight and upright (axial dystonia)). In particular, you may experience forward flexion of the head and neck (also called antecollis), forward bending of the lower back (also called camptocormia) or sideways bending of the back (also called pleurothotonus or Pisa Syndrome). If this happens, your doctor may want to change your medication.

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<sup>2</sup> The two bullet points have been merged and brackets have been added after 'dystonia'.