



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Pharmacovigilance Risk Assessment Committee (PRAC)

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

Adopted at the 6-9 June 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. Gabapentin – Respiratory depression without concomitant opioid use (EPITT no 18814)

#### Summary of product characteristics

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

Concomitant use with opioids

[...]

##### Respiratory depression

Gabapentin has been associated with severe respiratory depression. Patients with compromised respiratory function, respiratory or neurological disease, renal impairment, concomitant use of CNS depressants and the elderly might be at higher risk of experiencing this severe adverse reaction. Dose adjustments might be necessary in these patients.

##### 4.8. Undesirable effects

Respiratory, thoracic and mediastinal disorders

Frequency 'rare': Respiratory depression



## Package leaflet

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

#### Warnings and precautions

Talk to your doctor or pharmacist before taking <brand name>

[...]

- if you have nervous system disorders, respiratory disorders, or you are more than 65 years old, your doctor may prescribe you a different dosing regimen

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, tell your doctor (or pharmacist) if you are taking or have been recently taking any medicines for convulsions, sleeping disorders, depression, anxiety, or any other neurological or psychiatric problems.

### 4. Possible side effects

Contact your doctor immediately if you experience any of the following symptoms after taking this medicine as they can be serious:

[...]

- breathing problems, which if severe you may need emergency and intensive care to continue breathing normally

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

[...]

- Trouble breathing, shallow breaths (respiratory depression)