

# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION, EL(25)A/51

### Caution In Use

Issued 27 November 2025

Distribute to Pharmacy/Wholesaler Level

#### MARKETING AUTHORISATION HOLDER (MAH)

Special Concept Development UK Limited trading as RxFarma

#### MEDICINE DETAILS

##### Baclofen 10mg Tablets

PL 36722/0105

Active Ingredient: baclofen

SNOMED code: 40692211000001105

GTIN: 05060637641187

#### AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
EBJ25001F01	31/01/2028	84	14/08/2025
EBJ25002F01	31/01/2028	84	14/08/2025
EBJ25003F01	31/01/2028	84	14/08/2025

## Background

Special Concept Development UK Limited has informed the MHRA that the Patient Information Leaflet (PIL) for those batches in the table do not contain the correct safety information.

An [updated Summary of Product Characteristics](#) (SPC) is now available. The safety information missing in the PIL and previous SPC is summarised below:

#### PIL Section 2, What you need to know before you take baclofen

There have been reports of reduction in brain function (encephalopathy) in some patients taking baclofen at prescribed doses, which resolved after stopping the

medication. Symptoms include increased sleepiness, new onset of drowsiness, confusion, muscle jerks or coma. If you experience any of these symptoms, seek medical attention immediately. Your physician will decide whether baclofen has to be discontinued.

### **PIL Section 4, Possible side effects**

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

Reduction in brain function (encephalopathy)

### **SPC Section 4.4**

#### Encephalopathy

Cases of encephalopathy have been reported in patients receiving baclofen at therapeutic doses, which were reversible after treatment discontinuation. Symptoms included somnolence, depressed level of consciousness, confusion, myoclonus and coma.

If signs of encephalopathy are observed, baclofen should be discontinued.

### **SPC Section 4.8**

The following adverse reaction should be added under the SOC Nervous system disorders with a frequency not known.

SOC Nervous system disorders: Encephalopathy

### **Section 4.9**

The following adverse reaction(s) should be added as a symptom of baclofen overdose:

“Encephalopathy”

“Generalised slowing on EEG”

Symptoms: Prominent features are signs of central nervous depression or encephalopathy: somnolence, depressed level of consciousness, respiratory depression, coma and tinnitus.

Also liable to occur are: confusion, hallucinations, agitation, convulsion, abnormal electroencephalogram (burst suppression pattern and triphasic waves, generalised slowing on EEG), accommodation disorder, impaired pupillary reflex; generalised muscular hypotonia, myoclonia, hyporeflexia or areflexia; convulsions; peripheral vasodilatation, hypotension or hypertension, bradycardia or tachycardia, or cardiac arrhythmia; hypothermia; nausea, vomiting, diarrhoea, salivary hypersecretion; increased hepatic enzymes, sleep apnoea, rhabdomyolysis.

### Advice for Healthcare Professionals:

The quality of the tablets is not impacted by this issue; therefore the affected batches are not being recalled. Healthcare professionals are advised to review the information contained within this notification and take this into account when dispensing these products, especially for new patients.

If the medicine listed in this notification are dispensed, ensure that patients are aware of the missing information. Please see the [updated PIL](#) for the correct information.

Upon request, Special Concept Development UK Limited will provide hard copies of the to pharmacies so that any remaining stock in the dispensary can be supplemented with the correct PIL information. To request hard copies of the PIL, please contact [medinfo@rxfarma.co.uk](mailto:medinfo@rxfarma.co.uk) with your details, i.e. address, product with batch details, required number of leaflets.

Special Concept Development UK Limited has confirmed that all future batches will contain the correct PIL.

### Advice for Patients:

This issue is about missing information on the Patient Information leaflets (PILs) in the batches of Baclofen 10mg tablets included in the table. The quality of the tablets is not affected.

If you have concerns about the medicine you are using, please contact your healthcare professional in the first instance.

Patients who experience adverse reactions or have any questions about their medication should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

### Additional information:

For medical information enquiries please email [medinfo@rxfarma.co.uk](mailto:medinfo@rxfarma.co.uk) or telephone 08003580163.

For supply chain inquiries please contact email [supplychain@rxfarma.co.uk](mailto:supplychain@rxfarma.co.uk) or telephone 01923 332 777.

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

Defective Medicines Report Centre  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU

Telephone +44 (0)20 3080 6574  
[DMRC@mhra.gov.uk](mailto:DMRC@mhra.gov.uk)