



# MEDICINES NOTIFICATION

## CLASS 4 MEDICINES DEFECT INFORMATION

**Caution in Use**  
**Distribute to Pharmacy/Wholesaler Level**

Date: 15 November 2021

EL (21)A/29

Our Ref: MDR 247-10/21

Dear Healthcare Professional,

**RAD Neurim Pharmaceuticals EEC SARL, distributed by Flynn Pharma Ltd**

**Slentyto 1 mg prolonged-release tablets**

**EU/1/18/1318/001**  
**PLGB 52348/0003**

Batch Number	Expiry Date	Pack Size	First Distributed
1049309A	31/12/2021	60 tablets	01/04/2019
1049310	31/12/2021	60 tablets	05/03/2020
1049311	31/12/2021	60 tablets	01/10/2020
1049312	31/12/2021	60 tablets	04/03/2021
1051815	31/01/2022	60 tablets	06/07/2021
80419B	31/12/2021	60 tablets	12/03/2021
90287	30/09/2022	60 tablets	22/07/2021
10175A	31/05/2024	60 tablets	Not distributed yet
10186	31/05/2024	60 tablets	Not distributed yet

**Slentyto 5 mg prolonged-release tablets**

**EU/1/18/1318/003**  
**PLGB 52348/0004**

Batch Number	Expiry Date	Pack Size	First Distributed
00130	30/04/2023	30 tablets	15/07/2020
00409C	30/11/2023	30 tablets	Not distributed yet
10058	29/02/2024	30 tablets	Not distributed yet

Active Pharmaceutical Ingredient: melatonin



### **Brief description of the problem**

Flynn Pharma Ltd, distributors of Slenyto 1 mg and 5mg prolonged release tablets would like to notify you of an error with the patient information leaflets (PILs) that have been packaged in the above batches of products. These were an older version of the PIL which did not include the most up to date safety information. The information missing from the PILs is as below:

#### Section 2 Other medicines and Slenyto:

This should include “- beta-blockers (used to control blood pressure). These medicines should be taken in the morning.”

#### Section 6 Contents of the pack and other information:

In the section “What Slenyto looks like and contents of the pack”, the number “30 / ” is missing from the approved wording for the 1 mg tablet pack size and should state “Available in blister packs of 30 / 60 tablets.”

### **Advice for healthcare professionals**

There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Healthcare professionals are advised to exercise caution when dispensing the product and where possible, provide an updated PIL. Where available, Flynn Pharma Ltd will be providing the updated PIL with all future deliveries for the affected batches. The updated PIL is available via the electronic medicines compendium (EMC) website:

<https://www.medicines.org.uk/emc/files/pil.10023.pdf>

### **Further Information**

For more information, medical information queries or replacement PIL enquiries, please contact: Flynn Pharma Ltd Medical Information Department on 01438 727822, email – [medinfo@flynnpharma.com](mailto:medinfo@flynnpharma.com).

For stock control queries, please contact: Flynn Pharma Ltd on 01438 727822.

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**