

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy/Wholesaler Level

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.

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

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

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TO ALL CHEMISTS, DOCTORS ON THE LISTS

Pharmaceutical Services
2 Franklin Street
BELFAST
BT2 8DQ

Telephone No. 028 9536 0333

15th November 2021

Pharmaceutical website: <http://www.hscbusiness.hscni.net>