Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

M E D I C I N E S R E C A L L

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Patient/Pharmacy/Wholesaler Level Recall

Date: 08 February 2021 EL (21)A/02 Our Ref: MDR 332-01/21

Dear Healthcare Professional,

Grünenthal Ltd

Palexia 20 mg/ml Oral Solution PL 21727/0054

Batch Number	Expiry Date	Pack Size	First Distributed
00203N	02.2022	1 x 200ml	12.02.2018
00608N	02.2022	1 x 200ml	15.05.2018
00797N	02.2022	1 x 200ml	18.09.2018
01541I	02.2022	1 x 100ml	18.12.2017
00201N	02.2022	1 x 100ml	12.02.2018
00605N	02.2022	1 x 100ml	15.05.2018
00607N	02.2022	1 x 100ml	02.07.2018
01111N	02.2022	1 x 100ml	28.09.2018
01568N	04.2022	1 x 100ml	14.01.2019
00966P	04.2024	1 x 100ml	17.09.2019
01242P	04.2024	1 x 100ml	30.10.2019
01230P	06.2024	1 x 100ml	30.10.2019
01416P	06.2024	1 x 100ml	07.01.2020
00448R	01.2025	1 x 100ml	16.04.2020
01104R	01.2025	1 x 100ml	12.10.2020
01631R	09.2025	1 x 100ml	16.12.2020

Active Pharmaceutical Ingredient: Tapentadol Hydrocholoride

Schedule 2 Controlled Drug

Brief description of the problem
Grünenthal Ltd has informed us of a potential microbial contamination during routine stability testing for the batches listed in this recall. Due to the detection of possible *Burkholderia contaminans* the batches listed are being recalled as a precautionary measure. *Burkholderia contaminans* is a gram-negative bacterium and any potential infection may be more serious for immunocompromised patients and patients suffering from cystic fibrosis. This recall affects all batches of oral solution in the UK market that are still within their expiry date.

Advice for patients

- This medicine is intended for acute pain situations. Whilst the product has a 5-year shelf-life unopened, the bottle(s), once opened, should be used within 6 weeks.

- Patients who are currently administering doses from the bottle(s) of the affected batches should contact their doctor or pharmacist for consultation for a suitable clinical alternative medicine.

- Patients who have previously been dispensed the affected batches but are not on this medication at present should return the bottle(s) from the affected batches to a pharmacy for destruction, whenever possible based on the current UK Government guidelines for social distancing in relation to Coronavirus (COVID-19). See further information on COVID-19.

- If you experience any worsening of initial symptoms and other side-effects, or have any questions or concerns about your health, speak to your doctor or pharmacist. Report any suspected side effects via the Yellow Card Scheme.

Advice for healthcare professionals

- Stop supplying the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

- Pharmacists should contact all patients who have been dispensed this product between December 2017 to February 2021 to determine if any patients have the affected batches within their possession and to return these to the pharmacy as part of this recall.
    - If patients are confirmed to have the bottle(s) from the affected batches in their possession and they are currently administering dose, they should be signposted to this alert and informed to immediately contact their GP/Prescriber to consider withdrawal of the product, tapering of the dose and any suitable clinical alternatives.

- GPs/Prescribers who are contacted for replacement products should consider an appropriate review of patients currently administering opioid painkillers, due to the acute use of this product.

- GPs/Prescribers should be aware of potential medical concerns reported by patients who have been dispensed the affected batches. Any suspected side effects should be reported via the Yellow Card Scheme.

- When a prescription is needed for an alternative medicine, where possible, telephone appointments should be considered, based on the current UK Government guidelines for social distancing in relation to Coronavirus (COVID-19). Patients should be informed to follow the advice of their local GP practice/hospital and only attend where they are instructed to do so. See further information on COVID-19.

Further Information
For more information or medical information queries please contact +44 (0) 870 351 8960 or medicalinformationuk@grunenthal.com, Grünenthal Ltd,1 Stokenchurch Business Park, Ibstone Road, HP14 3FE

Recipients of this Medicines Recall 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

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