Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

4 June 2022

Dear Healthcare Professional,

DRUG ALERT CLASS 4 – 27 2022 – CLASS 4 MEDICINES DEFECT INFORMATION – CAUTION IN USE – NAPP PHARMACEUTICALS LTD – OXYCONTIN 20 MG PROLONGED RELEASE TABLETS

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 01 June 2022 EL (22)A/27 Our Ref: MDR 171-05/22

Dear Healthcare Professional,

Napp Pharmaceuticals Limited

OxyContin 20 mg prolonged release tablets			**PL 16950/0098**
Batch No	**Expiry Date**	**Pack Size**	**First Distributed**
250630	08 2024	56's	29/10/2021
250869	10 2024	56's	14/02/2022

Active Pharmaceutical Ingredient: Oxycodone Hydrochloride

Brief description of the problem
Napp Pharmaceuticals Limited have identified an error relating to the Braille printed on the cartons. The Braille message on the Oxycontin 20mg prolonged release tablets incorrectly states strength as 15mg.

Product	**Issue**	**Correct Braille**
Oxycontin 20mg prolonged release tablets, PL 16950/0098	Braille message incorrectly states strength as 15mg rather than 20mg.	The **correct** Braille message should read: 

Advice for healthcare professionals
The impacted products are within specification and there is no issue with product quality. Therefore, the affected batches are not being recalled.

Healthcare professionals should confirm when dispensing this product if this medicine is being collected on behalf of somebody else or if the patient will solely rely on Braille, and if needed explain the error in the Braille. The risk of an overdose remains low and any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Advice for patients
Two batches of Oxycontin 20 mg prolonged release tablets have an incorrect strength printed in Braille on the product pack. The pack contains 20 mg tablets as prescribed and the medicine itself is not affected.

Patients are reminded to take the tablets as per the instructions from your prescriber and those found on the dispensing label. OxyContin prolonged release tablets must be swallowed whole and not broken, chewed or crushed or split.

Further Information
For medical information and stock control queries please contact: Napp Pharmaceuticals – Tel. 01223 424444, email medicalinformationuk@napp.co.uk or supplies.uk@napp.co.uk

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

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