

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy / Wholesaler Level

Dear Healthcare Professional

Thornton & Ross Ltd

Methadone 1mg/mL Oral Solution BP - Sugar Free

PL 00240/0044

SNOMED Code 5196111000001108

Batch Number	Expiry Date	Pack Size	First Distributed
16LY	31/10/2025	6 x 500mL	21 Dec 2022
45LX	31/10/2025	6 x 500mL	17 Jan 2023
47LX	31/10/2025	6 x 500mL	27 Jan 2023
48LX	31/10/2025	6 x 500mL	03 Feb 2023
87MA	30/11/2025	6 x 500mL	Not yet distributed
90MA	30/11/2025	6 x 500mL	Not yet distributed
91MA	30/11/2025	6 x 500mL	Not yet distributed
08MB	30/11/2025	6 x 500mL	Not yet distributed
00MC	30/11/2025	6 x 500mL	Not yet distributed
44MD	31/12/2025	6 x 500mL	Not yet distributed
96MC	31/12/2025	6 x 500mL	Not yet distributed
92MA	31/12/2025	6 x 500mL	Not yet

			distributed
53MC	31/12/2025	6 x 500mL	Not yet distributed
52MC	31/12/2025	6 x 500mL	Not yet distributed
98MC	31/12/2025	6 x 500mL	Not yet distributed
99MC	31/12/2025	6 x 500mL	Not yet distributed
97MC	31/12/2025	6 x 500mL	Not yet distributed

Active Pharmaceutical Ingredient: methadone hydrochloride

Methadone Mixture 1mg/mL

PL 00240/0039

SNOMED Code 337711000001108

Batch Number	Expiry Date	Pack Size	First Distributed
19LY	31/10/2025	6 x 500mL	Not yet distributed
17LY	31/10/2025	6 x 500mL	Not yet distributed
18LY	31/10/2025	6 x 500mL	Not yet distributed
21LY	31/10/2025	6 x 500mL	Not yet distributed
20LY	31/10/2025	6 x 500mL	Not yet distributed
47MB	30/11/2025	6 x 500mL	Not yet distributed
19MB	30/11/2025	6 x 500mL	Not yet distributed
16MB	30/11/2025	6 x 500mL	Not yet distributed

Active Pharmaceutical Ingredient: methadone hydrochloride

Brief description of the problem

Thornton & Ross Ltd has informed the MHRA that specific batches of Methadone 1mg/mL Oral Solution BP Sugar Free have been packaged with the incorrect



Product Information Leaflet (PIL). The incorrect PIL is missing important safety information. Please see **Appendix 1 (Page 4-6 of this notification)** for full details of the missing information including the text in the current (erroneous) version of the leaflet packaged within the affected batches and the subsequent correct PIL text.

The batches listed as not yet distributed have also been packaged with the incorrect PIL and this affects both Methadone 1mg/mL Oral Solution BP Sugar Free and Methadone Mixture 1mg/mL. The MHRA, in discussion with the Department of Health and Social Care, considers these products critical for patients, therefore these batches will not be repackaged and continue to be distributed. They are therefore included in the notification.

Advice for healthcare professionals

There is no risk to product quality as a result of this issue and the affected batches on the market are not being recalled. Supervised consumption of methadone means that it is usually administered in the presence of a healthcare professional, who can advise the patient on important safety information and precautions.

For dispensing of products from all affected batches, healthcare professionals are advised to discuss the missing information with patients and provide a copy of the updated PIL, where appropriate. The missing information in the PIL provides additional safety information related to dependency, addiction, and withdrawal reactions; potential effects on hormones; safety information about pregnancy and breastfeeding; and potential interactions with other medicines. Links to the correct PILs are provided below:



Methadone 1mg/mL Oral Solution BP - Sugar Free:

<https://www.medicines.org.uk/emc/product/4905/pil>

Methadone Mixture 1mg/mL: <https://www.medicines.org.uk/emc/product/4907/pil>

Advice for patients

The Patient Information Leaflet (PIL) included in the pack with the above batches of these medicines does not contain the most up to date safety information. We have asked healthcare professionals to discuss the latest safety information with patients who are receiving medicines from these batches. Patients can also read the updated sections highlighted in **Appendix 1** or read the updated version of the PIL available online (links above).

You should not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. If you have any questions about your medicine or changes to the PIL or are concerned about side effects, talk to your healthcare professional. The quality of the medicine itself is not affected. As for all medicines, any suspected adverse reactions should also be reported via the MHRA's [Yellow Card scheme](#).

Further Information

For medical information queries please contact thorntonross@medinformation.co.uk. Upon request, Thornton & Ross Ltd will provide hard copies of the updated PIL to pharmacy teams.

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.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

TO ALL CHEMISTS, DOCTORS ON THE LISTS

Pharmaceutical Services
2 Franklin Street
BELFAST
BT2 8DQ

Telephone No. 028 9536 0333

7th March 2023

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