



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 07 March 2023

EL (23)A/07

Our Ref: MDR 146-02/23

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. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.



Medicines & Healthcare products
Regulatory Agency

Yours faithfully

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Appendix 1: Current PIL text and Correct PIL text (missing/changed information is highlighted in **bold**):

Section 1. What is the medicine and what does it do?

Current PIL text: This product works to prevent withdrawal symptoms in people who are addicted to opioid drugs such as heroin. It is important that it is taken regularly to reduce the risk of withdrawal symptoms occurring.

Correct PIL text: **This medicine contains methadone, which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.**

This medicine has been prescribed for you to prevent withdrawal symptoms following addiction to opioid drugs such as heroin. It is important that it is taken regularly to reduce the risk of withdrawal symptoms occurring.

It contains methadone which belongs to a class of medicines called opioids. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop and how to do this safely.

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Section 2. Before you take the medicine

Current PIL text:

Pregnancy and breast feeding

When pregnant it is especially important that you follow the instruction for treatment given by your doctor or clinic. Do not use this medicine whilst in labour or while breast feeding.

Correct PIL text:

Talk to your doctor or pharmacist if you have any of the following:

Weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenals producing too little of the hormone cortisol, and you may need to take hormone supplement.

Taking this medicine regularly, particularly for a long time, can lead to addiction.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.



Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Long-term use may cause decreased sex hormone levels and increased levels of the hormone prolactin. Contact your doctor if you experience symptoms such as decreased libido, impotence or absence of menstruation (amenorrhoea).

Other medicines and Methadone 1mg/mL Oral Solution/ Mixture

The risk of side effects increases, if you use methadone concomitantly with antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine, amitriptyline, clomipramine, imipramine, nortriptyline). Contact your doctor if you experience symptoms such as:

- mental-status changes (e.g. agitation, hallucinations, coma)
- fast heartbeat, unstable blood pressure, fever
- exaggeration of reflexes, impaired coordination, muscle stiffness
- gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea)

Also talk to your doctor or pharmacist if you are already taking any of the following:

- Metamizole, a medicine used to treat pain and fever.

Pregnancy and breast feeding

Do not take this medicine if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use this medicine during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take this medicine while you are breastfeeding as methadone passes into breast milk and will affect your baby.

Talk to your doctor if you are breastfeeding or thinking of breast-feeding while you are taking methadone as it may affect your baby. Monitor your baby for abnormal signs and symptoms such as increased drowsiness (more than usual), breathing difficulties or limpness. Consult your doctor immediately if you notice any of these symptoms.



Section 3. How to take the medicine

Current PIL text: If you take too much see a doctor straight away.

Effects when treatment is stopped

Stopping this medication abruptly will cause side effects, possibly severe. Follow the doctor's instructions carefully for coming off this medicine gradually.

Correct PIL text: Your prescriber should discuss your treatment and whether you need to continue taking this product at regular intervals. If you and your prescriber decide to stop treatment a plan will be put in place to gradually reduce the dose and stop taking the medicine to minimise the risk of withdrawal effects

If you take more medicine that you should see a doctor straight away. It can result in low blood sugar.

If you stop taking Methadone 1mg/mL

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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Section 4. Possible side effects

Current PIL text: Other possible side effects: When taken for a long period of time, it is possible that you may become dependent on Methadone Solution.

Correct PIL text: **Other possible side effects (frequency not known):**

- **Dependence and addiction**
- **Low blood sugar**

Drug Withdrawal

When you stop taking this medicine, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.