



Medicines & Healthcare products Regulatory Agency

Mexiletine - recall of 50mg, 100mg and 200mg capsules due to filling error

Reference: [NatPSA/2022/007/MHRA](#))

A manufacturing error has been detected for **all batches of Mexiletine hydrochloride Hard Capsules** made by Clinigen Healthcare Ltd. This problem could mean capsules of mexiletine may contain more or less medicine than they should.

Mexiletine hydrochloride 50mg Hard Capsules, PL 31644/0027

- Batch Number 2111216
- Expiry Date 02/2024*

*Per correction by Clinigen Healthcare Ltd, an update was made to correct the expiry date to reflect 02/2024

Mexiletine hydrochloride 100mg Hard Capsules, PL 31644/0028

- Batch Number 2111217
- Expiry Date 04/2024

Mexiletine hydrochloride 200mg Hard Capsules, PL 31644/0029

- Batch Number 2111218
- Expiry Date 04/2024

Advice for patients

- If you are taking mexiletine, check to see if you have any of the above batches at home. The batch number and expiry date can be found on the outer carton and also at the end of each blister strip. If you are unsure or unable to locate the batch number and expiry date, please contact your pharmacist for further advice.
- **Do not to stop taking mexiletine without consulting your healthcare professional. The risks of suddenly stopping medication for ventricular arrhythmias is higher than the potential risk presented by taking capsules containing too much or too little mexiletine.**
- Your pharmacist, GP/doctor, or other healthcare professional will contact you to make sure you get a new prescription for an alternative product before you need to take your medicine back. You can contact them directly if you are worried.
- There has been no reported harm associated with this issue, but patients should be aware of possible symptoms of too much or too little mexiletine (below).

A smaller dose than you need could result in worsening control of cardiac arrhythmia (irregular heartbeat). The patient alert card supplied with your medication provides important information on the symptoms of arrhythmia. These symptoms can include feeling like your heart is beating too hard or too fast (palpitations), chest pain, shortness of breath, light-headedness, dizziness or fainting.

A larger dose than you need could increase side effects. The symptoms of overdose include feeling sick, hypotension (low blood pressure), paraesthesia (tingling of the extremities), hallucinations (seeing or hearing something that is not present), convulsions (fits) or, feeling like your heart is beating irregularly (slower or faster).

Seek urgent medical attention if you experience any of the symptoms suggestive of an underdose or overdose.

- Additionally, you may need closer monitoring particularly after changes in your mexiletine treatment. Please follow your doctor's instructions.
- If you are in any doubt, please contact your pharmacist, GP/doctor, or other healthcare professionals for advice as to whether you are in possession of an affected batch.

Patients are advised to complete your name and your doctors name and contact details on the patient alert card supplied with the medication and keep it at all times, for instance in a wallet or a purse.

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