National Patient Safety Alert

Medicines & Healthcare products Regulatory Agency

Recall of Mexiletine hydrochloride 50mg, 100mg and 200 mg Hard Capsules, Clinigen Healthcare Ltd due to a potential for underdosing and/or overdosing

Date of Issue:	04-Aug-22	**Reference No:**	NatPSA/2022/007/MHRA

This alert is for action by: primary and secondary care, specifically those involved in pharmacy services, including dispensing general practices.

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards) supported by Chief Pharmacists and the clinical lead for cardiology, as well as leaders in general practice and community pharmacy

DMRC Medicines Defect Classification	NatPSA equivalent to Class 1 Recall Notification

Explanation of identified safety issue:

Clinigen Healthcare Ltd is initiating a recall of three batches of Mexiletine hydrochloride hard capsules due to a potential risk of underdose or overdose, which could have consequences for the safety of patients.

Stability testing identified that some individual capsules on the market may fall outside the individual fill-weight range. This means that there is the potential for some capsules to contain too little active ingredient and for some to contain too much active ingredient. This could result in potential underdosing and overdosing.

Page 2 lists potential clinical consequences, noting the need for vigilance of symptoms of arrhythmias.

Clinigen Healthcare Ltd has confirmed that no alternative batches of mexiletine hydrochloride 50mg, 100mg or 200mg hard capsules will be available until later in the year, therefore the recall of these batches from patients should only be considered where patients have access to appropriate alternative products. See below for more information on resupplying patients with alternative products.

Patients should be advised not to stop any treatments without consulting their relevant healthcare professional. The risks of suddenly stopping medication for ventricular arrhythmias is higher than the potential risk presented by too much or too little of the active ingredient in the capsule.

Another licensed mexiletine product is available as Namuscla 167mg (equivalent to 200mg mexiletine hydrochloride) hard capsules, however, this is indicated for the symptomatic treatment of myotonia in adult patients with non-dystrophic myotonic disorders and is not indicated for treatment of life-threatening ventricular arrhythmias and supply would be considered “off-label" use (i.e. use outside of its licensed indication).

Actions required

Actions to complete by 12-Aug-22:

The action to recall should be coordinated by the Chief Pharmacist/Superintendent Pharmacist/Responsible Pharmacist and Dispensing GPs in the first instance.

1. Stop supplying the impacted batch immediately. Quarantine all remaining stock and return it to your supplier/MAH using your supplier’s approved process.

2. Identify and immediately contact all patients who have been dispensed the impacted batch and ask them to confirm if they have remaining stock within their possession. If batch traceability information is not available, all patients dispensed this product since 10 February 2022 should be contacted.

3. If the pharmacist identifies any patients with an impacted batch, they should, in the first instance, contact the patient’s GP and discuss alternative mexiletine treatment of the patient. As this is a specialist use product and patients may require monitoring, other clinicians and healthcare professionals may need to be involved.

4. Discuss the risk of cardiac arrhythmias with patients and advise them to seek urgent medical attention if they experience any new or worsening of symptoms of an arrhythmia including palpitations, angina pain, chest discomfort, dizziness and loss of consciousness.

Healthcare professionals may also consider the use of unlicensed medicines where appropriate. See the MHRA recall notice for more information.

Additional information:

For further detail, resources and supporting materials see: www.gov.uk/drug-device-alerts

Product Information: Clinigen Healthcare Ltd.

	Mexiletine hydrochloride 50mg Hard Capsules PL 31644/0027	Mexiletine hydrochloride 100mg Hard Capsules PL 31644/0028	Mexiletine hydrochloride 200mg Hard Capsules PL 31644/0029
Batch Number	2111216	2111217	2111218
Expiry Date	02/2024*	04/2024	04/2024
Pack Size	84 capsules	84 capsules	100 capsules
First Distributed	10/02/2022	10/02/2022	10/02/2022

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

Defective Medicines Report Centre Reference: MDR 109-07/22

Healthcare professionals should be aware of the following clinical considerations related to the potential risk of either under- or overdosing.

Underdosing:

- Underdose could lead to lack of efficacy, which could consequently result in a ventricular arrhythmia
- There needs to be an increased vigilance for symptoms of arrhythmias (palpitation, chest pain, shortness of breath, light-headedness, and syncope) reported by a patient, which may be due to underdosing.
- A patient alert card is supplied with the product in each pack. Advise patients to complete their and their doctor's name and contact details on the patient alert card and keep it with them at all times, for instance in a wallet or a purse.
- Discuss the risk of cardiac arrhythmias with patients and tell them to seek urgent medical attention if they experience any new or worsening of symptoms of an arrhythmia including palpitations, angina pain, chest discomfort, dizziness and loss of consciousness. The HCP guide for management of risk of cardiac arrythmia is available here: https://www.medicines.org.uk/emc/product/13306/rmms

Overdosing:

- The clinical features include nausea, hypotension, bradycardia, paraesthesia, left bundle branch block, asystole, convulsions, which may be life-threatening and can be fatal.
- Refer to the approved Summary of Product Characteristics (SmPC) for treatment recommendations: https://www.medicines.org.uk/emc/product/13306/smpc.

Any patients experiencing any of the symptoms listed above should be advised to immediately contact their nearest accident and emergency centre. Healthcare professionals should note that some patients may have an implantable cardioverter-defibrillator (ICD) fitted and additional monitoring should be considered where appropriate.

Additional monitoring should be considered for all patients due to the potential for under- and/or overdosing to have occurred and as per product literature to monitor electrolytes, full blood counts and liver function tests during treatment and where alternative products may be provided.

Patients who have the impacted batch can be provided with a supplementary letter to explain any potential observations relating to under- and/or overdosing. See more information in the accompanying PDFs with this NatPSA.

Advice to provide to patients

Patients should not stop taking mexiletine hydrochloride hard capsules without consulting their relevant 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 of the active ingredient. Patients need to be aware of possible symptoms of having taken too much or too little of the active ingredient in the capsule.

This alert includes the more relevant critical information, however, please see further guidance in the MHRA notice in relation to this recall.

Reference Information:

1. Class 1 Medicines Recall Notification including patient specific information – Click Here

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Please check website www.gov.uk/drug-device-alerts for when actions should be ceased or advice to check for date restriction are lifted.