Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 hours
Patient/Pharmacy/Wholesaler Level Recall

Date: 06 June 2024 EL (24)A/20 Our Ref: DMRC-30746702

Dear Healthcare Professional,

Desitin Pharma UK Ltd

Lamotrigine Desitin 10mg/ml Oral Suspension **PL 14040/0040**

SNOMED Code 42751111000001102

Batch No	Expiry Date	Pack Size	First Distributed
024171A1	31/01/2026	300ml	07-May-2024
024172A1	31/01/2026	300ml	07-May-2024
024173A1	31/01/2026	300ml	07-May-2024
024174A1	31/01/2026	300ml	07-May-2024
024223A1	28/02/2026	300ml	07-May-2024
024224A1	28/02/2026	300ml	07-May-2024
024225A1	28/02/2026	300ml	07-May-2024
024226A1	28/02/2026	300ml	07-May-2024
024227A1	28/02/2026	300ml	07-May-2024
024237A1	28/02/2026	300ml	07-May-2024
024238A1	28/02/2026	300ml	07-May-2024
024239A1	28/02/2026	300ml	07-May-2024
024243A1	28/02/2026	300ml	07-May-2024
024244A1	28/02/2026	300ml	07-May-2024
024245A1	28/02/2026	300ml	07-May-2024
024246A1	28/02/2026	300ml	07-May-2024
024247A1	28/02/2026	300ml	07-May-2024
024304A1	31/03/2026	300ml	31-May-2024
024305A1	31/03/2026	300ml	31-May-2024
024306A1	31/03/2026	300ml	31-May-2024
024307A1	31/03/2026	300ml	31-May-2024
024308A1	31/03/2026	300ml	31-May-2024

Active Pharmaceutical Ingredient: Lamotrigine

Brief description of the problem
Desitin Pharma UK Ltd is recalling all batches of Lamotrigine Desitin 10mg/ml Oral Suspension as a precautionary measure due to an out of specification observation in the appearance of samples during routine stability testing. Desitin Pharma UK Ltd believe that this is a homogeneity issue with the batches manufactured. This issue means that there is the potential for some doses to have too little active ingredient (lamotrigine) in them and some doses to contain too much active ingredient. This could result in potential underdosing or overdosing. No such confirmed reports have been received to date. The root cause of this issue is under investigation, but based on the potential for a homogeneity issue, the product is being recalled as a precautionary measure.

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Advice for healthcare professionals
Stop supplying the impacted batch immediately. Quarantine all remaining stock and return it to your supplier/MAH using your supplier's approved process.

Patients should be advised not to stop their medication as this may cause seizures to start again or happen more often or last longer than before.

1. Pharmacists should identify and immediately contact all patients who have been dispensed the impacted batches 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 from 07 May 2024 should be contacted. Patients and carers should be reminded that suddenly stopping an epilepsy medicine may cause seizures to start again or happen more often or last longer than before.
    a. If the pharmacist identifies any patients with an impacted product, they should, in the first instance, contact the patient's GP or prescriber and discuss alternative lamotrigine treatment for the patient. As patients may require monitoring, other clinicians and healthcare professionals may need to be involved.

2. Prescribers, clinicians, and other healthcare professionals involved in the prescribing/monitoring of patients who are using lamotrigine oral suspension should contact their patients and/or carers directly to ensure that their treatment is reviewed, and a suitable alternative product is prescribed.

Desitin Pharma UK Ltd has confirmed that Lamotrigine Desitin 10mg/ml Oral Suspension (PL 14040/0040) was first distributed on 07 May 2024 and therefore prior to this, this specific product was not available in the UK. Desitin UK Pharma Ltd have also confirmed that 282 packs have been sold from wholesalers to pharmacies directly and the remaining stock (circa 4800 units) will not be distributed.

Healthcare professionals should be aware that there are no other licensed lamotrigine oral suspension/solutions available, and patients will require substitution with other licensed formulations including tablets, dispersible tablets, and/or an unlicensed product (specials). See details in Further Information section.

Lamotrigine has been designated as a Category 2 Antiepileptic drug (AED). See further information in the MHRA Drug Safety Update. https://www.gov.uk/drug-safety-update/antiepileptic-drugs-updated-advice-on-switching-between-different-manufacturers-products

Advice for patients
The MHRA have been made aware of a potential issue with Lamotrigine Desitin 10mg/ml Oral Suspension. The issue identified by the manufacturer means that there is the potential for some doses to have too little lamotrigine in them and some doses to contain too much active ingredient. This could result in potential underdosing or overdosing. These batches are being recalled as a precaution; we are not aware of any confirmed cases of patient harm.

Your GP, specialist, pharmacist, or other healthcare professional will contact you to make sure you get a new prescription for an alternative product. Once you have a replacement, you should return your Lamotrigine Desitin 10mg/ml Oral Suspension to any pharmacy as part of the recall. You can contact your healthcare professional directly if you are worried but you should keep taking your medicine as advised until you get an alternative.

Never stop taking medicines such as lamotrigine without medical advice, especially if they are being used for epilepsy. Suddenly stopping an epilepsy medicine may cause your seizures to start again or happen more often or last longer than before.

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Patients who experience adverse reactions, have a sudden worsening of their clinical condition, or have any questions about medication used by you or someone you care for, should seek medical attention. If you have any concerns about your or your child's health, consult with your healthcare professional. Continue to take your medicine as prescribed.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Further Information
For medical information enquiries please contact medinfo@desitin.co.uk. For stock control enquiries please contact alison.wilton@desitin.co.uk.

Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Unlicensed imports do not undergo any central quality assessment or suitability evaluation. Therefore, any import must be locally assessed in line with local unlicensed medicines processes.

Please see the links below for further information:

- The supply of unlicensed medicinal products, Medicines and Healthcare products Regulatory Agency (MHRA)
- Professional Guidance for the Procurement and Supply of Specials, Royal Pharmaceutical Society
- Prescribing unlicensed medicines, General Medical Council (GMC)

When prescribing a product that is not licensed in the UK due to a supply issue with the licensed alternative prescribers it must be indicated on the FP10 prescription that an unlicensed product is required. This can be done in one of the following two ways:

- Electronic prescriptions – if the required unlicensed product is shown on electronic prescribing systems, GPs should select:
  - *Add name of drug* (imported)
- Paper prescriptions – where the unlicensed product is not shown on electronic prescribing systems, GPs should use a paper prescription and annotate with the following wording: "**special order**".

Recipients of this Medicines Recall 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 and further action.

Yours faithfully

Defective Medicines Report Centre
10 South Colonnade
Canary Wharf
London
E14 4PU
Telephone +44 (0)20 3080 6574
DMRC@mhra.gov.uk