Medicines & Healthcare products Regulatory Agency

M E D I C I N E S N O T I F I C A T I O N

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy / Wholesaler Level

Date: 25 October 2022 EL (22)A/45 Our Ref: MDR 014-10/22

Dear Healthcare Professional,

Recordati Rare Diseases

Pedea 5 mg/ml solution for injection

PLGB 15266/0024

EU/1/04/284/001

Batch No	Expiry Date	Pack Size	First Distributed
PD0G24E-07	10/2024	Box of 4 ampoules	07/09/2022
PD0G24E-10	10/2024	Box of 4 ampoules	Not yet distributed
PF0G04E-03	10/2024	Box of 4 ampoules	Not yet distributed

Active Pharmaceutical Ingredient: Ibuprofen

Brief description of the problem:
Recordati Rare Diseases T/A Recordati Rare Diseases UK Ltd has made the MHRA aware that the above batches of Pedea 5 mg/ml solution for injection have been packaged with the incorrect Product Information Leaflet (PIL). The incorrect PIL does not contain important safety information relating to severe skin reactions. In addition, the current Summary of Product Characteristics (SmPC) does not include the relevant safety information.

Missing information from the PIL:

Section 2. What you need to know before you use Pedea	Warnings and precautions - Take special care with Pedea Skin reactions Serious skin reactions have been reported in association with Pedea treatment. You should stop taking Pedea and seek medical attention immediately, if you develop any skin rash, lesions of the mucous membranes, blisters or other signs of allergy since this can be the first signs of a very serious skin reaction. See section 4.
Section 4. Possible side effects	Frequency “Not known” A red, scaly widespread rash with bumps under the skin and blisters mainly localized on the skin folds, trunk, and upper extremities accompanied by fever at the initiation of treatment (acute generalised exanthematous pustulosis). Stop using Pedea if you develop these symptoms and seek medical attention immediately. See also section 2.

Missing information from the SmPC:

Section 4.4. Special warnings and precautions for use	Severe skin reactions Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported rarely in association with the use of NSAIDSs (see section 4.8). Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Acute generalised exanthematous pustulosis (AGEP) has been reported in relation to ibuprofen-containing products. Ibuprofen should be discontinued, at the first appearance of signs and symptoms of severe skin reactions, such as skin rash, mucosal lesions, or any other sign of hypersensitivity.
Section 4.8. Undesirable effects	Skin and subcutaneous tissue disorders Frequency: Not known: Acute generalised exanthematous pustulosis (AGEP)

Advice for healthcare professionals:
There is no risk to product quality as a result of this issue, therefore the affected batches are not being recalled. Healthcare professionals will note that batch PD0G24E-10 and batch PF0G04E-03 are not yet distributed. The MHRA, in discussion with the Department of Health and Social Care, considers this product critical for patients, therefore these batches are included in the notification. Recordati Rare Diseases T/A Recordati Rare Diseases UK Ltd has confirmed that all future batches will contain the correct PIL and the SmPC details will be corrected.

Severe skin reactions are a well-known side effect of ibuprofen-containing medicines and non-steroidal anti-inflammatory medicines. Healthcare professionals should monitor patients who have been administered Pedea 5 mg/ml solution for injection and should discontinue the treatment course if any of the following side effects occur: skin rash, mucosal lesions, toxic epidermal necrolysis, exfoliative dermatitis, or any other sign of hypersensitivity.

Advice for patients:
Patients are not required to take any action at this time. This product is administered by healthcare professionals directly. If you have concerns about a medicine you may be using, please contact your healthcare professional. Severe skin reactions are a well-known side effect of ibuprofen-containing medicines and non-steroidal anti-inflammatory medicines.

Patients should continue to be aware that in rare cases severe skin reactions occur. These include skin rash, mucosal lesions, toxic epidermal necrolysis, exfoliative dermatitis, or any other sign of hypersensitivity. If you notice any of these symptoms or have any concerns, please contact your healthcare professional immediately.

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Further Information:
For further information, including medical enquiries and stock information, please contact:

Recordati Rare Diseases UK Ltd (local representative, WDA(H): 15720) on Tel: +44 (0)1491 414333 or +33 1 47 73 64 58 or email: RRDmedinfo@recordati.com

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 hospital pharmacists and pediatric doctors and nurses working in hospital setting for information.

Yours faithfully

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