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IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

29 August 2023

Dear Healthcare Professional,

DRUG ALERT CLASS 4 DRUG ALERT 31 2023 – CLASS 4 MEDICINES DEFECT INFORMATION – CAUTION IN USE – GALDERMA (UK) LTD – LOCERYL 5% W/V MEDICATED NAIL LACQUER (5.0ML)

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team

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: 29 August 2023 EL(23)A/31 Our Ref: MDR 087-06/23

Dear Healthcare Professional,

Galderma (U.K.) Limited

Loceryl 5% w/v Medicated Nail Lacquer (5.0 ml) **PL 10590/0042**

SNOMED Code 757311000001109

Batch Number	Expiry Date	Pack Size	First Distributed in UK
2212421*	05 / 2025	1 x 5.0ml	19-Aug-2022

Active Pharmaceutical Ingredient: 5% w/v amorolfine in the form of hydrochloride

Brief description of the issue
Galderma (U.K.) Limited has informed the MHRA that a pallet of Loceryl 5% w/v Medicated Nail Lacquer from a batch licensed only for distribution in Ireland has been inadvertently placed into the UK supply chain due to a warehousing error at their UK pre-wholesaler. Although Loceryl is a registered medicine in both Ireland and the UK, there are differences between these products in the product labelling and Patient Information Leaflet (PIL) packaged with the medicine.

Details of the key packaging differences for Ireland (under Irish product authorisation number PA 22743/009/001; *SKU number 023299) versus the UK product (PL 10590/0042; SKU number 023271), which the company and MHRA have risk-assessed as having minimal safety implications for the patient, are described below.

- Bottle Labelling
  - The bottle label should state the requirement to protect the product from heat.

- PIL Section 2 ('What you need to know before you use Loceryl')
  - The instruction, in the event of a serious allergic reaction (a reaction which is described above the warnings and precautions section), to 'stop applying the product, immediately remove the product with a nail varnish remover or the cleaning swabs provided with the package' is missing.
  - 'Tongue or throat swelling' is missing from the serious allergic reaction symptoms above the warnings and precautions section.
  - The statement "*One gram of Loceryl contains 552 mg of alcohol (ethanol), which is equivalent to 55.2 % w/w. It may cause a burning a sensation on damaged skin. Ethanol is a flammable substance and should not be used near an open flame, a lit cigarette or some devices (e.g. hair dryers).*" is missing from the 'Important information about some of

the ingredients' section. However, the 'Possible side effects' section of the PIL (section 4) does forewarn that a burning sensation may occur in the area around the nail (with a frequency of very rare) and the patient is instructed (in PIL section 5 – 'How to store Loceryl') to keep the pack away from heat.

- PIL Section 4 ('Possible side effects')
  - 'Systemic allergic reaction (a serious allergic reaction that can be associated with swelling of the face, lips, tongue or throat, difficulty breathing and/or a severe skin rash)' wording is missing from the 'Unknown frequency of occurrence' section.
  - The contact details provided in the leaflet for reporting side effects/adverse events relate to the Irish authority (HPRA) rather than the UK authority (MHRA).

- Administrative details
  - The carton, bottle label and PIL display the Marketing Authorisation Holder (MAH) name and address and Marketing Authorisation (MA) number as registered in Ireland rather than those registered in the UK.

Advice for healthcare professionals
Healthcare professionals are advised to exercise caution when dispensing the above batch of Loceryl 5% w/v Medicated Nail Lacquer (as packaged in the Irish livery). Where possible, please provide the current UK-approved copy of the PIL to the patient and remind the patient to read the leaflet in its entirety before using the medicine. Please reiterate to patients that this product contains ethanol, which is a flammable substance, and should not be used near an open flame, a lit cigarette or some devices (for example, hair dryers).

The Marketing Authorisation Holder can supply copies of the correct PIL on request; a copy of the UK PIL is available via the following link: Loceryl 5% w/v Medicated Nail Lacquer - Patient Information Leaflet (PIL) - (emc) (medicines.org.uk)

Advice for patients
There is missing information from the Patient Information Leaflet that accompanies certain packs of batch 2212421 of Loceryl 5% w/v Medicated Nail Lacquer (5.0 ml) – i.e. the Irish packs inadvertently distributed in the UK. The missing information has been detailed in this notification.

You can ask your pharmacist for a copy of the correct leaflet or you can access it directly by clicking here. Please ensure that you read the information on the packaging and in the leaflet carefully before using the product.

If you experience symptoms of a systemic allergic reaction while using the medicated nail lacquer (swelling of the face, lips, tongue or throat, difficulty breathing and/or a severe skin rash) then you should stop applying the product and immediately remove it with a nail varnish remover or the cleaning swabs provided with the package. Always seek medical advice if you have an allergic reaction.

Loceryl medicated nail lacquer also contains ethanol. Ethanol is a flammable substance and should not be used near an open flame, a lit cigarette or some devices (for example, hair dryers).

Loceryl is a Prescription Only Medicine (POM), (medicines that have to be prescribed by a doctor or other authorised health professional), and should be used as directed. If you have any questions,

please consult your GP or pharmacist. Any suspected adverse reactions or side effects should be reported to the MHRA's Yellow Card scheme.

Further Information
If you require more information, have further medical information enquiries (including replacement PIL enquiries) then please e-mail: medinfo.uk@galderma.com. For stock control queries, please contact: sales.uk@galderma.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 community pharmacists and dispensing general practitioners for information.

Yours faithfully

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