Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 Hours
Pharmacy/Wholesaler Level Recall

Date: 27 January 2020 EL (20)A/02 Our Ref: MDR 112-01/20

Dear Healthcare Professional,

LEO Laboratories Ltd. T/A LEO Pharma

Product	Marketing Authorisation Number
Picato 150 mcg/g gel ▼	EU/1/12/796/001
Picato 500 mcg/g gel ▼	EU/1/12/796/002

Batch Number	Expiry Date	Pack Size	First Distributed
A69570A	Jan-20	3 x 0.47g tubes	18-Apr-18
A69570B	Jan-20	3 x 0.47g tubes	06-Jun-18
A72947A	Feb-20	3 x 0.47g tubes	06-Jun-18
A75024A	Apr-20	3 x 0.47g tubes	18-Jul-18
A78808A	May-20	3 x 0.47g tubes	05-Sep-18
A80602B	Jun-20	3 x 0.47g tubes	12-Sep-18
A80602A	Jun-20	3 x 0.47g tubes	12-Sep-18
A89440A	Nov-20	3 x 0.47g tubes	22-Jan-19
A92248A	Dec-20	3 x 0.47g tubes	11-Feb-19
A98938A	Mar-21	3 x 0.47g tubes	16-May-19
C01098A	Apr-21	3 x 0.47g tubes	24-Jun-19
C10894A	Aug-21	3 x 0.47g tubes	22-Oct-19
C14179A	Oct-21	3 x 0.47g tubes	06-Dec-19
A76669A	Apr-20	2 x 0.47g tubes	22-Aug-18
A88113A	Oct-20	2 x 0.47g tubes	11-Dec-18
A98419A	Mar-21	2 x 0.47g tubes	16-May-19
C03413A	May-21	2 x 0.47g tubes	29-Aug-19
C11902A	Sep-21	2 x 0.47g tubes	08-Nov-19

Active Pharmaceutical Ingredient: ingenol mebutate

LEO Laboratories Ltd (T/A LEO Pharma) is recalling all unexpired stock of the above products from pharmacies and wholesalers as a precautionary measure due to concerns on the possible risk of skin malignancy. The recall is a precautionary measure following the suspension of the marketing authorisation of Picato (ingenol mebutate), while investigations are ongoing.

Advice for healthcare professionals

- Stop supplying the above products immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

- Stop prescribing Picato and consider other treatment options as appropriate. For patients who have recently been prescribed Picato, advise patients to be vigilant for any skin lesions developing and to seek medical advice promptly should any occur.

▼ Picato is subject to additional monitoring to allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Further information

Replacement stock of this product will not be available. Please contact your supplier/wholesaler for details on the returns process.

Credit for returned products must be obtained from the supplier from where the product was purchased. If you have any questions in regard to return of stock, then please contact your local Alliance Healthcare Service Centre Customer Services team.

For medical information enquiries please contact LEO Pharma Medical Information Department on 01844 347 333 and press 2 for Medical Information, or by email at medical-info.uk@leo-pharma.com.

Recipients should bring it to the attention of relevant contacts by copy of this letter.

NHS Regional teams are asked to forward this to relevant clinics, general practitioners and community pharmacists.

Yours faithfully

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