D R U G A L E R T

CLASS 2 MEDICINES RECALL

**Action Within 48 Hours**

**Pharmacy/Wholesaler Level Recall**

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

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Dear Healthcare Professional,

**LEO Laboratories Ltd. T/A LEO Pharma**

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

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| --- | --- | --- | --- |
| **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](http://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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