

## South East London Area Prescribing Committee

**Temporary withdrawal of formulary recommendation number 010  
(issued June 2014):  
Ingenol mebutate gel (Picato®) for the cutaneous treatment of non-  
hyperkeratotic, nonhypertrophic actinic keratosis (AK) in adults**

This formulary recommendation has been **temporarily withdrawn** as the European Medicines Agency (EMA) has **suspended** the use of ingenol mebutate gel (Picato®) as a precaution while a review of skin cancer risk continues. Picato® is a topical gel for treating the skin condition actinic keratosis.

The EMA's safety committee (PRAC\*) is currently reviewing data on skin cancer in patients using Picato®. Final results from a study comparing Picato with imiquimod indicate a higher occurrence of skin cancer in the treatment area with Picato® than with imiquimod.

In view of this, the EMA has recommended that **patients stop using Picato®**, while it continues its review of the medicine's safety.

The PRAC will continue its review and when the review has concluded, the EMA will provide updated guidance to patients and healthcare professionals.

The decision to temporarily withdraw the formulary recommendation will be reviewed once the EMA review has concluded.

Please refer to the [CAS alert](#) and [EMA information](#) for further information and detail.

Please contact [contactus@selondonics.nhs.uk](mailto:contactus@selondonics.nhs.uk) for further information.

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\*PRAC is the EMA's Pharmacovigilance Risk Assessment Committee