17 April 2020
EMA/194393/2020

EMA review of Picato concludes medicine's risks outweigh its benefits

EMA's safety committee (PRAC) has confirmed that Picato (ingenol mebutate), a gel for treating the skin condition actinic keratosis, may increase the risk of skin cancer and concluded that the risks of the medicine outweigh its benefits.

The conclusions are based on a review of all available data on the risk of skin cancer in patients using Picato, including results of a study comparing Picato with imiquimod (another medicine for actinic keratosis). The study showed a higher occurrence of skin cancers, especially squamous cell carcinoma, in areas of skin treated with Picato than in areas treated with imiquimod.

The Committee also considered that Picato's effectiveness is not maintained over time and noted that other treatment options are available for actinic keratosis.

Picato is no longer authorised in the EU. In January 2020, Picato was suspended as a precaution while the review was underway. On 11 February 2020, the marketing authorisation was withdrawn at the request of LEO Laboratories Ltd, the company that marketed the medicine.

Patients who have been treated with Picato should look out for unusual skin changes or growths, which may occur from weeks to months after use, and seek medical advice if any occur. Patients who have questions or concerns about their treatment should consult their doctor or pharmacist.

More about the medicine

Picato was available as a gel which was applied to skin areas affected by actinic keratosis. It was used when the outer layer of the affected skin was not thickened or raised. Actinic keratosis is caused by too much sunlight exposure and can turn into skin cancer.

Picato was authorised for use in the EU in November 2012.

More about the procedure

The review of Picato has been initiated at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

On 16 January 2020, while the review was ongoing, EMA's Pharmacovigilance Risk Assessment Committee (PRAC) recommended suspension of the marketing authorisation of Picato. The European Commission issued a legally binding decision to suspend the marketing authorisation on 17 January 2020.

On 11 February 2020, the European Commission withdrew the marketing authorisation of the medicine at the request of the marketing authorisation holder LEO Laboratories Ltd.

The PRAC has now concluded its review of the available evidence on Picato. The PRAC recommendation will be sent to EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency’s opinion.

The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.