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Review of data on skin cancer with Picato

EMA is reviewing data on skin cancer in patients using Picato (ingenol mebutate), a gel for treating actinic keratosis, a skin condition caused by too much sunlight exposure.

The review was triggered by data from several studies showing a higher number of skin cancer cases, including cases of squamous cell carcinoma, in patients using Picato.

The product information for Picato already contains a warning about reports of one type of skin tumour (keratoacanthoma) and, following a separate review, this warning is currently being updated to mention skin cancers called basal cell carcinoma, Bowen's disease and squamous cell carcinoma.

Healthcare professionals are advised to use Picato with caution in patients who have had skin cancer in the past. In addition, patients should continue to watch out for any skin lesions and inform their doctor immediately if they notice anything unusual. Patients who have questions or concerns about their treatment should contact their doctor.

In order to conclude on whether Picato increases the risk of skin cancer, the EMA's safety committee (PRAC) will now carry out a thorough review of all available data, including from ongoing studies. The Committee will assess the impact of the data on the benefit-risk balance of Picato and recommend whether the medicine's marketing authorisation in the EU should be amended.

More about the medicine

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

Picato has been authorised for use in the EU since 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.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set

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of recommendations. The PRAC recommendations will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt an 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.