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EPAR summary for the public

Picato

ingenol mebutate

This is a summary of the European public assessment report (EPAR) for Picato. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Picato.

What is Picato?

Picato is a medicine containing the active substance ingenol mebutate. It is available as a gel in two strengths (150 micrograms/g and 500 micrograms/g).

What is Picato used for?

Picato is used to treat adults with actinic keratosis. Actinic keratosis is a skin lesion that develops after too much exposure to sunlight. Picato is used when the outer layer of the skin affected by actinic keratosis is not thickened or raised.

The medicine can only be obtained with a prescription.

How is Picato used?

Picato gel is applied to the affected skin areas. When the affected areas are the face, scalp and upper part of the neck, Picato (150 micrograms/g) should be applied once a day for three consecutive days. When the affected areas are the trunk, extremities and lower part of the neck, the higher strength Picato (500 micrograms/g) should be applied once a day for two consecutive days. A new tube of Picato gel should be used for each application. The content of one tube covers a treatment area of 25 cm^2.

For further information on how to use Picato see the package leaflet.

The patient's response to treatment can be assessed approximately eight weeks after treatment.

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How does Picato work?

The exact way Picato works is not fully understood. It is thought that the active substance in Picato, ingenol mebutate, works in two different ways. Once applied and absorbed by the skin cells, ingenol mebutate has a direct toxic effect on the cell as well as promoting an inflammatory response. Together, these actions lead to the death of the cells affected by actinic keratosis.

How has Picato been studied?

The effects of Picato were first tested in experimental models before being studied in humans.

Picato (150 microgram/g) has been studied in two main studies involving 547 adults with actinic keratosis affecting the face and scalp, where it was applied once a day for three consecutive days.

Picato (500 microgram/g) has been studied in two studies involving 458 adults with actinic keratosis affecting the trunk and extremities, where it was applied once a day for two consecutive days.

In all four studies, Picato was compared with vehicle (a gel without active substance). The main measure of effectiveness was the number of patients whose skin was completely cleared of the actinic keratosis eight weeks after treatment.

What benefit has Picato shown during the studies?

Picato was shown to be effective in clearing actinic keratosis from the skin.

For actinic keratosis affecting the face and scalp, the first study showed that the skin completely cleared in 47% (67 out of 142) of patients treated with Picato, compared with 5% (7 out of 136) of patients treated with placebo. In the second study the skin completely cleared in 37% (50 out of 135) of patients treated with Picato, compared with 2% (3 out of 134) of patients treated with placebo.

For actinic keratosis of the trunk and extremities, the first study showed that the skin cleared completely in 28% (35 out of 126) of patients treated with Picato, compared with 5% (6 out of 129) of patients treated with placebo. In the second study, the skin cleared in 42% (42 out of 100) of patients treated with Picato, compared with 5% (5 out of 103) of patients treated with placebo.

What is the risk associated with Picato?

The most frequently reported side effects are skin reactions at the application site of Picato, including erythema (reddening of the skin), flaking or scaling, crusting, swelling, vesiculation or pustulation (blisters), and erosion or ulceration (wearing away of outer skin layer or open sore of the skin). Following the application of Picato, most patients (more than 95%) experienced one or more local skin responses. Infection at the application site was also reported when treating the face and scalp. For the full list of all side effects reported with Picato, see the package leaflet.

Picato must not be used in people who are hypersensitive (allergic) to ingenol mebutate or any of the other ingredients.

Why has Picato been approved?

The CHMP noted that treatment with Picato has a beneficial effect. There were no major safety concerns with Picato and the side effects seen were mostly local skin reactions which, although they affected most patients, usually resolved within two to four weeks of treatment depending on the location. In addition, the CHMP considered the fact that Picato can be self-applied and that treatment is

of short duration as an advantage. The CHMP therefore decided that Picato's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Picato

The European Commission granted a marketing authorisation valid throughout the European Union for Picato on 15 November 2012.

The full EPAR for Picato can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Picato, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2012.