Abbreviated Prescribing Information for Picato® ▼ 150 micrograms/gram (mcg/g) and 500 micrograms/gram (mcg/g) gel

Please refer to the full Summary of Product Characteristics (SmPC) (www.medicines.org.uk/emc) before prescribing

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.
Indication: Cutaneous treatment of non-hyperkeratotic, non-hypertrophic actinic keratosis in adults.
Active ingredients: Picato 150 micrograms/gram (mcg/g) gel: each gram of gel contains 150 mcg ingenol mebutate; each tube contains 70 mcg ingenol mebutate in 0.47 g of gel. Picato 500 mcg/g: each gram of gel contains 500 mcg ingenol mebutate; each tube contains 235 mcg ingenol mebutate in 0.47 g of gel.
Dosage and administration: Application to the face and scalp in adults (150 mcg/g): One tube to be applied once daily to affected area for 3 consecutive days. Application to the trunk and extremities in adults (500 mcg/g): One tube to be applied once daily to affected area for 2 consecutive days. *Paediatrics:* No relevant use. *Elderly:* No dose adjustment required. The contents of one tube covers a treatment area of 25 cm^2 (eg 5 cm x 5 cm); this should be applied to one treatment area of 25 cm^2. Tube for single use only; discard after use. Squeeze the gel from the tube onto a fingertip and spread evenly over entire treatment area, allowing to dry for 15 minutes. Treatment of neck: if more than half of the treatment area is located in the upper part of the neck, posology for face and scalp should be used. If more than half of the treatment area is located in the lower part of the neck, posology for trunk and extremities should be used. If an area on the face or scalp and another area on the trunk or extremities are simultaneously treated, advise patients to ensure they use the appropriate strengths. Care should be exercised not to apply the 500 mcg/g gel on the face or scalp as this could lead to a higher incidence of local skin responses. Advise patients to wash hands with soap and water immediately after applying gel and between topical applications if two different areas require different strengths. If treating hands, patients should only wash fingertip used to apply the gel. Avoid washing and touching treated area for 6 hours after applying gel. After this period, treatment area may be washed using mild soap and water. Gel should not be applied immediately after taking a shower or less than 2 hours before bedtime. Treated area should not be covered with occlusive bandages after applying gel. Optimal therapeutic effect can be assessed after approximately 8 weeks. A repeat treatment course of Picato can be given if an incomplete response is seen at a follow-up examination after 8 weeks or if lesions that are cleared at this examination recur in subsequent examinations. Treatment data in immunocompromised patients not available, but systemic risks not expected since ingenol mebutate is not absorbed systemically.
Contraindications: Hypersensitivity to any of the constituents.
Precautions and warnings: Contact with the eyes can cause chemical conjunctivitis and corneal burns. Wash hands thoroughly after applying the gel and following any contact with the treated area to avoid inadvertent transfer to the eyes. If accidental exposure occurs, flush eyes with large amounts of water and seek medical care as soon as possible. Eye disorders such as eye pain, eye lid oedema and periorbital oedema are expected to occur after accidental exposure. Gel must not be ingested. If accidental ingestion occurs, the patient should drink plenty of water and seek medical care. Administration not recommended until skin healed from treatment with any previous medicinal product or surgery. Do not apply to open wounds or damaged skin. Do not use near the eyes, inside nostrils, inside ears or on lips. Local skin responses (LSRs) such as erythema, flaking/scaling and crusting should be expected to occur after application. LSRs are transient and typically occur within 1 day of treatment initiation and peak in intensity up to 1 week following completion of treatment. LSRs typically resolve within 2 weeks of treatment initiation when treating face and scalp and within 4 weeks of treatment initiation when treating trunk and extremities. Treatment effect may not be adequately assessed until resolution of LSRs. Ingenol mebutate did not demonstrate any potential for photo irritation or photo allergic effects during studies to assess the effect of UV irradiation. However, due to nature of disease, excessive exposure to sunlight (including sunlamps and tanning beds) should be avoided or minimised. Clinically atypical lesions or suspicious lesions for malignancy should be biopsied to determine appropriate treatment.
Drug interactions: No interaction studies performed. Interactions with systemically absorbed medicinal products considered unlikely as Picato is not absorbed systemically.
Fertility, pregnancy and lactation: No data on the use of ingenol mebutate in pregnant women. Animal studies showed slight embryo-foetal toxicity. Risks to humans receiving cutaneous treatment with ingenol mebutate considered unlikely as no systemic absorption. As a precautionary measure, it is preferable to avoid use of the gel during pregnancy. No effects on the breast-fed newborn/infant anticipated. Instruct nursing mother that physical contact between her newborn/infant and the treated area should be avoided for 6 hours after application of gel. No fertility studies have been performed.
Side effects: Most frequently reported adverse drug reactions (ADRs) are LSRs. Following application of ingenol mebutate, most patients (>95%) experienced one or more LSRs. *ADRs observed for face and scalp (150 mcg/g)*: *Very common:* Application site: pustules, erosion, vesicles, swelling, exfoliation, scab, erythema, pain (including burning). *Common:* Headache, eye lid/periorbital oedema (application site swelling on the face or scalp may gravitate to the eye area), application site: infection, pruritus, irritation. *Uncommon:* Hypersensitivity (including angioedema), chemical conjunctivitis, corneal burn (post-marketing reports in connection with accidental eye exposure), eye pain, application site: discharge, paraesthesia, ulcer, pigmentation changes. *ADRs observed for trunk and extremities (500 mcg/g): Very common:* Application site: pustules, erosion, vesicles, swelling, exfoliation, scab, erythema. *Common:* Application site: pain (including burning), pruritus, irritation. *Uncommon:* Hypersensitivity (including angioedema), chemical conjunctivitis, corneal burn (post-marketing reports in connection with accidental eye exposure), application site: paraesthesia, ulcer, pigmentation changes, warmth.
See SmPC for a full list of side effects.
Precautions for storage: Store in a refrigerator (2°C-8°C). Tubes should be discarded after first opening.
Legal category: POM.
Marketing Authorisation Number and Holder: Picato® 150 mcg/g gel - EU/1/12/796/001; Picato® 500 mcg/g gel - EU/1/12/796/002. LEO Pharma A/S, Ballerup, Denmark. **Basic NHS Price:** Picato® 150 mcg/g gel, 3 x 0.47 g, £65.00; Picato® 500 mcg/g gel, 2 x 0.47 g, £65.00.
Last revised: April 2016.

Further information can be found in the Summary of Product Characteristics or from: LEO Pharma, Horizon, Honey Lane, Hurley, Maidenhead, Berkshire SL6 6RJ.
e-mail: medical-info.uk@leo-pharma.com

Reporting of Suspected Adverse Reactions
Adverse events should be reported. Reporting forms and information can be found at: www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Drug Safety at LEO Pharma by calling +44 (0)1844 347333 or e-mail medical-info.uk@leo-pharma.com

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