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1. What Picato® is and what it is used for
Picato contains the active substance ingenol mebutate. This medicine is used for topical (on the skin) treatment of actinic keratosis, also called solar keratosis, in adults. Actinic keratoses are rough areas of skin found in people who have been exposed to too much sunshine over the course of their lives. The medicine is used for treatment of actinic keratoses on the foamy, arms, hands and legs.

2. What you need to know before you use Picato®
Do not use Picato®
- If you are allergic to ingenol mebutate or any of the other ingredients of this medicine (listed in section 6).
- If you have any of the following conditions: severe inflammation or irritation of the skin, blood diseases, skin lupus, psoriasis, skin rash, skin infections, skin cancer, skin irritation due to sunlight, or skin changes due to sunlight.
- If you have a bleeding disorder, or a disorder affecting the way blood clots.
- If you have any other medical conditions that may make it unsafe to use this medicine.
- If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor for advice before using this medicine. You should avoid the use of Picato if you are pregnant.
- If you are breast-feeding, avoid physical contact between the baby and the treated area for 6 hours after application of this medicine.
- If you are pregnant or breast-feeding, think you may be pregnant.
- If you are allergic to any of the ingredients of this medicine (listed in section 6).
- If you have any further questions, ask your doctor or pharmacist. You should avoid the use of Picato if you are allergic to any of the ingredients of this medicine.
- If you have any further questions, ask your doctor or pharmacist.

Warnings and precautions
- Do not rub the gel into the wound or on the lips. Wash your hands thoroughly after applying the gel. Do not rub the gel into the wound or on the lips. Avoid contact with the eyes.
- Do not get Picato in your ears. Wash your hands thoroughly after applying the gel. Do not rub the gel into the wound or on the lips.
- Do not apply more gel than your doctor has advised. Do not apply more gel than your doctor has advised. If you apply more gel than advised, wash your hands thoroughly after applying the gel.
- Do not apply Picato to the lips. Do not apply Picato to the lips.
- Do not use Picato near the mouth or throat. Do not use Picato near the mouth or throat.
- Do not apply Picato on open wounds or damaged skin. Do not apply Picato on open wounds or damaged skin. Apply Picato only to areas of skin that is not damaged.
- Do not apply Picato near the eyes or mouth. Do not apply Picato near the eyes or mouth.
- Do not apply Picato near the nose. Do not apply Picato near the nose.
- Do not apply Picato on the scalp, hair, or short hair. Do not apply Picato on the scalp, hair, or short hair.
- Do not wash the areas where you applied the gel for at least 6 hours after applying the gel. Do not wash the areas where you applied the gel for at least 6 hours after applying the gel.
- Do not touch the treatment area yourself or allow anyone on any pets to touch the treatment area for a period of 6 hours after applying the gel. Do not touch the treatment area yourself or allow anyone on any pets to touch the treatment area for a period of 6 hours after applying the gel.

Uncommon side effects, may affect up to 1 in 10 people:
- Tingling or numbness (paresthesia)
- Discharge (secretion) of fluid
- Change in skin colour (pigmentation change)
- Eye pain
- Allergic reaction that may include swelling of the mouth, tongue or throat
- Pain or irritation to the surface of the eye (conjunctiva)
- Rashes

Very common side effects, may affect up to 1 in 10 people:
- Injury or irritation to the surface of the eye (cornea, conjunctiva) following accidental exposure.
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Other side effects:
- Change in skin colour (pigmentation change)
- Warmth,
- Irritation (pruritus)
- Headache.
- Other side effects:
- Change in skin colour (pigmentation change)
- Warmth,
- Irritation (pruritus)
- Headache.

4. Possible side effects
If you use more Picato than you should
- Consult your doctor or pharmacist if you have used more than Picato should.

If you forget to use Picato
Please contact your doctor or pharmacist if you have used Picato.
- Consult your doctor or pharmacist if you have used Picato.

5. How to store Picato®
- The full effect of Picato can be evaluated approximately 8 weeks after treatment.

- Store in a refrigerator (2°C-8°C).
- Store in a refrigerator (2°C-8°C).

Other possible side effects when treating the face and scalp:
- Swelling
- Uncommon side effects on the treatment area, may affect more than 1 in 10 people:
- Pain (including application site burning).
- Redness due to widening of the small blood vessels (erythema).
For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

- **Belgium/Бельгия/Belgien**
  - **Leo Pharma N.V., S.A.**
  - Tel: +32 2 3 740 788

- **Burma/Бирма/Birma**
  - **Birma Ltd.**
  - Tel: +95 2 9190 136

- **Česka republika/Чеська Республика/чешская Республика**
  - **Leo Pharma s.r.o.**
  - Tel: +420 225 992 272

- **Danmark/Дания/Данциг**
  - **Leo Pharma A/S**
  - TP: +45 70 22 40 11

- **Deutschland/Германия/Германия**
  - **Leo Pharma GmbH**
  - Tel: +49 6102 2010

- **Dáil/Дания/Дания**
  - **Leo Pharma A/S**
  - Tel: +45 64 94 58 88

- **Egipto/Югославия/Египет**
  - **Leo Pharmaceutics, S.A.**
  - Tel: +30 210 68 34322

- **España/Егио/Испания**
  - **Laboratorios Leo Pharma, S.A.**
  - Tel: +34 93 221 3368

- **França/Франция/Франция**
  - **Leo Pharma**
  - Tel: +33 1 3014 4000

- **Гренландия/Гренландия/Grenlandia**
  - **Remedia d.o.o.**
  - Tel: +385 1 3779 070

- **Ireland/Ирландия/Iрландия**
  - **Leo Laboratories Ltd**
  - Tel: +353 81 1 490 824

- **Izland/Исландия/Исландия**
  - **Vestur Ltd.**
  - Sími: +354 535 7000

- **İtalya/Италия/Италия**
  - **Leo Pharma S.p.A.**
  - Tel: +39 06 526 5000

- **Kína/Китай/Китай**
  - **Kompac**
  - Tel: +86 21 5838 0000

- **Kroatia/Хорватия/Хорватия**
  - **Remedia d.o.o.**
  - Tel: +387 3267 1056

- **Latvija/Латвия/Латвия**
  - **Leo Pharma A/S**
  - Tel: +371 45 94 58 88

- **Lietuva/Литва/Литва**
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  - Tel: +370 45 94 58 88

This leaflet was last revised in January 2017.

Detailed information on this medicine is available on the European Medicines Agency web site: [http://www.ema.europa.eu](http://www.ema.europa.eu)