What is this medicine?
Picato® is a medicine used for treating small non-melanoma skin cancers like actinic keratoses, usually on the face. It is applied as a 150 micrograms/g gel

What is in this leaflet:
This leaflet contains information about:
- How to use Picato®
- What you need to know before you use Picato®
- Possible side effects

What you need to know before you use Picato®

Warnings and precautions
- Do not apply this medicine internally, to the area near the eye or to open wounds.
- Do not apply this medicine if you are allergic to ingenol mebutate or any of the other ingredients of this medicine.
- Do not apply Picato® to the area under your tongue or in your mouth.
- Wash your hands with soap and water immediately after applying Picato® to the treatment area.
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the container. If you use too much, wash it off with soap and water and seek medical assistance as needed.

Children and adolescents
Picato should not be used by children or adolescents under 18 years of age.

Other medicines and Picato®
Tell your doctor or pharmacist if you are using, have recently used or have to use any other medications.
- Make sure that your skin has healed from any other treatments before beginning to use Picato®. Do not apply Picato® to open wounds or damaged skin.
- If you are pregnant or planning to become pregnant, talk to your doctor about the risks and benefits of using this medicine.
- Only use Picato® if your doctor has prescribed it for you.
- It is important to follow your doctor’s instructions closely.

Driving and using machines
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- If you have any other questions on the use of this medicine, ask your doctor or pharmacist.
- It is very important that you talk to your doctor or pharmacist if you forget to use Picato®.
- If you have any unusual side effects while using Picato®, contact your doctor or pharmacist.

Instructions for use:
- Open a new tube each time you use Picato®. Remove the cover of the tube before use.
- Apply the content of one tube to one area of 25 cm² (e.g. 5 cm x 5 cm).
- Apply the gel to the treatment area for 6 hours after applying the gel.
- Do not wash the skin areas where you applied the gel for at least 6 hours after you apply it.
- Do not touch the treated area yourself or allow anyone or any pets to touch the treatment area for a period of 6 hours after applying the gel.
- The skin of the treatment area may appear wet or water tight bandages after you have applied this medicine.
- The total effects of Picato® can be evaluated approximately 8 weeks after treatment.

If you use more Picato® than you should
- Please contact your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Uncommon side effects may affect up to 1 in 100 people:
- Tingling or numbness (paresthesia)
- Open sore (ulcer)
- Change in skin colour (pigmentation change)
- Warmth
- Allergic reaction that may include swelling of the mouth, tongue or throat
- Worry or irritation to the surface of the eye (liria), conjunctival following accidental exposure
- Rare side effects may affect up to 1 in 1000 people:
- Changes in the face and scalp

If you forget to use Picato®
Please contact your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You can also report side effects directly via the national reporting systems:
- For Ireland, via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
  Tel: +353 1 6764971
  Fax: +353 1 6762517
  Email: medicinfo@hpра.ie
  Website: www.hpra.ie
  For the United Kingdom, via the Yellow Card Scheme, Website: www.yellowcard.gov.uk/or直接on the safety of this medicine.

5. How to store Picato®
Keep the medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the container and tube, after Expo. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C-8°C)
- For single use only. Do not use the tubes once opened.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information
What Picato contains
The active substance is ingenol mebutate. Each gram of gel contains 150 micrograms of ingenol mebutate. Each tube of Picato 150 micrograms/g gel contains 2% of ingenol mebutate.
- The active substance is ingenol mebutate.
- The other ingredients are loperamide, hydroxyethylcellulose, citric acid monohydrate, sodium chloride, citric acid, benzyl alcohol, purified water.
- What Picato looks like and contents of the pack: Picato 150 micrograms/g gel is clear and colourless and each tube contains 2% of ingenol mebutate.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
LEO Laboratories Ltd.
285 Cashel Road, Crumlin, Dublin 12
Ireland
Manufacturer
LEO Laboratories Ltd.
285 Cashel Road, Crumlin, Dublin 12
Ireland

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[Image of package leaflet: Information for the patient Picato® 150 micrograms/gram gel]
For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

**Belgium/Belgique/Belgien**
LEO Pharma N.V./S.A.
Tel/Tél: +32 3 740 7888

**Bulgaria**
Borovska
Tel.: +359 2 9158 136

**Czechia**
Leo Pharma s.r.o.
Tel: +420 2 956 272

**Denmark**
LEO Pharma A/S
Tel: +45 70 24 49 11

**Deutschland**
LEO Pharma GmbH
Tel: +49 61 05 20 10

**Estonia**
LEO Pharma A/S
Tel: +372 49 94 58 88

**El Salvador**
Leo Pharmaceutical S.A.S.
Tel: +506 222 5346

**France**
LEO Pharma
Tel: +33 1 30 14 40 02

**Greece**
Remedia d.o.o.
Tel: +30 210 279 77 70

**Ireland**
LEO Laboratories Ltd.
Tel: +353 1 4 60 0024

**Island**
Vestfriki
Tel: +354 3 93 70 00

**Italy**
LEO Pharma S.p.A.
Tel: +39 0 36 02 30000

**Köper**
Thé Sainsbury’s Markets Importers Co. Ltd.
Tel: +337 23 13 10 06

**Latvia**
LEO Pharma A/S
Tel: +45 94 94 58 88

**Lithuania**
LEO Pharma A/S
Tel: +45 94 94 58 88

This leaflet was last revised in January 2017.

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**Belgium/Belgique/Belgien**
LEO Pharma N.V./S.A.
Tel/Tél: +32 3 740 7888

**Luxembourg/Luxemburg**
LEO Pharma N.V./S.A.
Tel/Tél: +32 3 740 7888

**Maccarese**
LEO Pharma
Tel: +39 0 6 526 25 000

**Malta**
PHARMACO COS LTD
Tel: +356 2 116 1870

**Netherlands**
LEO Pharma B.V.
Tel: +31 20 104 141

**Norway**
LEO Pharma AS
Tel: +47 22 51 72 38

**Slovakia**
LEO Pharma Slovakia
Tel: +422 224 94 00

**Spain**
Laboratorios LEO Pharma, S.A.
Tel: +34 9 32 22 53 66

**Sweden**
LEO Pharma AB
Tel: +46 40 352 20 00

**United Kingdom**
The Star Medicines Importers Co. Ltd.
Tel: +44 1844 34 73 33

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