

Package leaflet: Information for the patient

Picato[®] 500 micrograms/gram gel

ingenol mebutate

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Picato[®] is and what it is used for
2. What you need to know before you use Picato[®]
3. How to use Picato[®]
4. Possible side effects
5. How to store Picato[®]
6. Contents of the pack and other information

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 lifetime. Picato 500 micrograms/gram gel is used for actinic keratosis on the body, 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).

Warnings and precautions

- Do not get Picato in your eyes. Wash your hands thoroughly after you have applied the gel. Wash your hands again if you happen to touch the area where you applied the gel. Take care not to transfer gel from the treatment area into your eyes. In the event of accidental contact, remove the gel by rinsing with plenty of water and seek medical assistance as soon as possible.
- Do not swallow this medicine. Drink plenty of water if you accidentally swallow this medicine and seek medical assistance.
- Make sure that your skin has healed from any other treatments or surgery before using this medicine. Do not apply Picato on open wounds or damaged skin.
- Do not apply this medicine internally, to the area near the eyes, to the inside of the nostrils, the inside of the ear or on the lips.
- Avoid sunlight as much as possible (including sunlamps and tanning beds).
- This medicine is intended to treat one area of 25 cm² for two days. This should be strictly adhered to.
- Do not apply more gel than your doctor has advised.
- You should expect to get local skin reactions, such as reddening and swelling, after treatment with this medicine (see section 4). Contact your doctor if these local skin reactions get severe.

Children and adolescents

Actinic keratosis does not occur in children, and this medicine must not be used in children and adolescents under 18 years of age.

Other medicines and Picato

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

If you have previously used Picato or other similar medicines tell your doctor before starting the treatment.

Pregnancy and breast-feeding

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.

Driving and using machines

This medicine does not have any effect on your ability to drive or to use machines.

3. How to use Picato[®]

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

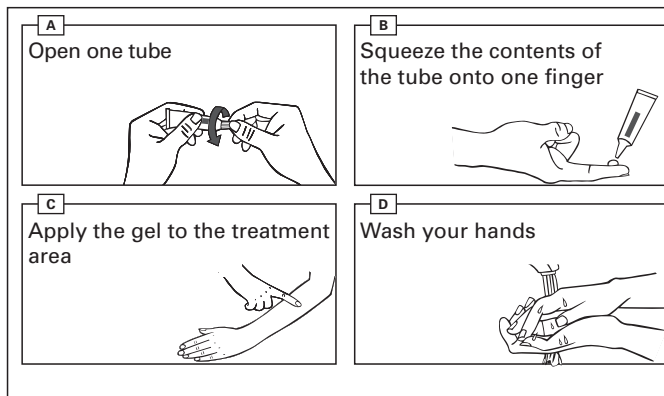
If you have been prescribed two different strengths for treatment of two different areas you should make sure that you use the prescribed strength on the correct area.

- Treatment of actinic keratosis on the body, arms, hands and legs is one tube of Picato 500 micrograms/g gel (containing 235 micrograms of ingenol mebutate) once a day for 2 days in a row.

Instructions for use:

- Open a new tube each time you use this medicine. Remove the cap from the tube just before use.
- Squeeze the gel from one tube onto a fingertip.
- Apply the content of one tube to one area of 25 cm² (e.g. 5 cm x 5 cm).
- Gently rub the gel onto the treatment area.
- Allow the area to dry for 15 minutes. Avoid touching the treatment area for 6 hours after applying your medicine.
- Wash your hands with soap and water immediately after applying the gel, and also in between administrations if prescribed two different strengths for two different areas. If you are treating your hands you should only wash the fingertip which you used for applying the gel.
- Do not apply this medicine immediately after taking a shower or less than 2 hours before bedtime.

- Do not wash the areas where you applied the gel for at least 6 hours after you apply it.
- Do not touch the treatment area yourself or allow anyone or any pets to touch the treatment area for a period of 6 hours after applying the gel.
- Do not cover the treated area with air- or water-tight bandages after you have applied this medicine.
- The full effect 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 have used more Picato than you should.

If you forget to use Picato

Please contact your doctor or pharmacist if you forget to use Picato.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

After using this medicine the skin where you apply it is likely to get red, peel and have scabs. These side effects most often occur within one day after applying this medicine. The side effects may get worse for up to 1 week after you have stopped using this medicine. They will usually get better within 4 weeks from when you started the treatment.

Infection of the skin in the treatment area can occur (has been reported as a common side effect, which may affect up to 1 in 10 people, when treating the face and scalp).

Swelling of the application site is very common (has been reported in more than 1 in 10 people). Application site swelling on the face or scalp may gravitate to the eye area.

Should the symptoms described above intensify beyond the first week after you have stopped using this medicine, or if there is discharge of pus, you might have an infection and should contact your doctor or pharmacist.

The most frequently occurring side effects when treating the face and scalp:

Very common side effects on the treatment area, may affect more than 1 in 10 people:

- On the treatment area:
- Some of the outer layer of your skin may wear away (erosion)
 - Blisters (vesicles, pustules)
 - Swelling
 - Peeling (exfoliation)
 - Scabs
 - Redness due to widening of the small blood vessels (erythema)
 - Pain (including application site burning).

The most frequently occurring side effects when treating the trunk and extremities:

Very common side effects on the treatment area, may affect more than 1 in 10 people:

- On the treatment area:
- Some of the outer layer of your skin may wear away (erosion)
 - Blisters (vesicles, pustules)
 - Swelling
 - Peeling (exfoliation)
 - Scabs
 - Redness due to widening of the small blood vessels (erythema).

Other possible side effects when treating the face and scalp:

Common side effects, may affect up to 1 in 10 people:

- On the treatment area:
- Itching (pruritus)
 - Irritation.

Other side effects:

- Swelling of the area around the eye (periorbital oedema)
- Swelling (oedema) of your eye lid
- Headache.

Uncommon side effects, may affect up to 1 in 100 people:

On the treatment area:

- Tingling or numbness (paraesthesia)
- Open sores (ulcer)
- Discharge (secretion) of fluid
- Change in skin colour (pigmentation change).

Other side effects:

- Eye pain
- Allergic reaction that may include swelling of the mouth, tongue or throat
- Injury or irritation to the surface of the eye (cornea, conjunctiva) following accidental exposure.

Rare side effects, may affect up to 1 in 1000 people:

On the treatment area:

- Scarring.

Other possible side effects when treating the trunk and extremities:

Common side effects, may affect up to 1 in 10 people:

On the treatment area:

- Itching (pruritus)
- Irritation
- Pain (including application site burning).

Uncommon side effects, may affect up to 1 in 100 people:

On the treatment area:

- Tingling or numbness (paraesthesia)
- Open sores (ulcer)
- Change in skin colour (pigmentation change)
- Warmth.

Other side effects:

- Allergic reaction that may include swelling of the mouth, tongue or throat
- Injury or irritation to the surface of the eye (cornea, conjunctiva) following accidental exposure.

Rare side effects, may affect up to 1 in 1000 people:

On the treatment area:

- Scarring.

Reporting of side effects

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 system.

For Ireland, via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
E-mail: medsafety@hpra.ie

For the United Kingdom, via the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Picato[®]

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 carton and tube after EXP. 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 re-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 500 micrograms of ingenol mebutate. Each tube contains 235 micrograms of ingenol mebutate in 0.47 g of gel.

- The other ingredients are isopropyl alcohol, hydroxyethylcellulose, citric acid monohydrate, sodium citrate, benzyl alcohol, purified water.

What Picato looks like and contents of the pack

Picato 500 micrograms/g gel is clear and colourless and each carton contains 2 tubes with 0.47 g of gel each.

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
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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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>



LEO



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BACK PANEL