

Patient Information
PICATO[®] (Pih-KAY-toe)
(ingenol mebutate)
gel, 0.015%, 0.05%

Important: For use on the skin only (topical). Do not use Picato gel in, around, or near your eyes, lips, mouth, or vagina.

What is Picato gel?

- Picato gel, 0.015% is a prescription medicine used on the skin to treat actinic keratosis on the face or scalp.
- Picato gel, 0.05% is a prescription medicine used on the skin to treat actinic keratosis on the body or arms and legs. It is not known if Picato gel is safe and effective for the treatment of actinic keratosis in children less than 18 years of age.

Who should not use Picato gel?

Do not use Picato gel if you are allergic to ingenol mebutate or any of the ingredients in Picato gel. See the end of this leaflet for a list of the ingredients in Picato gel.

What should I tell my healthcare provider before using Picato gel?

Before using Picato gel, tell your healthcare provider about all of your medical conditions, including if you:

- are being treated or have been treated for actinic keratosis with other medicines or surgery. You should not use Picato gel until your skin has healed from other treatments.
- have other skin problems or sunburn in the treatment area.
- are pregnant or plan to become pregnant. It is not known if Picato gel can harm your unborn baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

How should I use Picato gel?

- Use Picato gel exactly as your healthcare provider tells you. **Picato gel is for skin use only.**
- Your healthcare provider will tell you where to apply Picato gel, and how often, and how long to apply it. **Do not apply Picato gel to other areas.**
- Do not use more Picato gel than you need to cover the treatment area. Using too much Picato gel, or using it too often, or for too long can increase your chances for having a severe skin reaction or other side effects.
- **Do not get Picato gel in, around, or near your eyes.** Do not touch your eyes while you are applying Picato gel.
 - Wash your hands well with soap and water after applying Picato gel. After applying Picato gel, be careful to keep Picato gel on the treated area from coming into contact with your eyes. Irritation may happen if you get Picato gel in your eyes.
 - **If you accidentally get Picato gel in your eyes**, flush them with large amounts of water and get medical care as soon as possible. Also see "What are the possible side effects of Picato gel?"
- Do not get Picato gel in, around, or near your mouth or lips.
- To help prevent accidental transfer of Picato gel to other areas of your body or to another person:
 - allow the treated area to dry for 15 minutes after you apply Picato gel.
 - avoid washing and touching the treated area, or doing activities that cause a lot of sweating, for 6 hours after treatment. After 6 hours, you may wash the area with a mild soap and water.
- Only use a tube of Picato gel 1 time. Throw away any open tube of Picato gel after use even if there is medicine still left in it.
- See the Instructions for Use that comes with your Picato gel for information about the right way to apply it.

What are the possible side effects of Picato gel?

Picato gel may cause serious or severe side effects including:

- **Eye problems can happen if Picato[®] gel gets in your eyes.** Eye problems may include severe eye pain, swelling or drooping of your eyelids, or swelling around your eyes. If you accidentally get Picato[®] gel in your eyes, flush them with large amounts of water and get medical care as soon as possible.
- **Serious allergic reactions.** Serious allergic reactions have happened with Picato gel, and in some cases have required treatment in a hospital. See "Who should not use Picato Gel?" Get medical help right away if you get any of the following symptoms of a serious allergic reaction:
 - swelling of the lips or tongue
 - chest tightness
 - trouble breathing or wheezing
 - dizziness or passing out
- **Local skin reactions.** Skin reactions in the treatment area are common with Picato gel. You may get a skin reaction such as mild redness, flaking or scaling, crusting, or swelling. You may also see changes in your skin color (pigmentation changes) and scarring where Picato gel is applied. Call your healthcare provider if you get skin redness, flaking or scaling, crusting, or swelling that is more severe, or if you get blisters, pus, ulcers or breakdown of your skin.

The most common side effects with Picato gel include:

- local skin reactions, see “Local skin reactions” above
- pain, itching, or skin irritation at the treatment area
- infection at the treatment area
- swelling around the eyes
- nose and throat irritation
- headache

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Picato gel. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to LEO Pharma Inc. at 1-877-494-4536.

How should I store Picato gel?

- Store Picato gel in a refrigerator at 36°F to 46°F (2°C to 8°C). Do not freeze.
- Picato gel has an expiration date (exp) marked on the end of the tube. Do not use the gel after this date.
- Safely throw away used Picato gel tubes in household trash.

Keep Picato gel and all medicines out of the reach of children.**General information about the safe and effective use of Picato gel.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Picato gel for a condition for which it was not prescribed. Do not give Picato gel to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Picato gel that is written for health professionals.

What are the ingredients in Picato gel?

Active ingredient: ingenol mebutate

Inactive ingredients: isopropyl alcohol, hydroxyethyl cellulose, citric acid monohydrate, sodium citrate, benzyl alcohol and purified water

Manufactured by: LEO Laboratories Ltd. (LEO Pharma) 285 Cashel Road, Dublin 12 Ireland

Distributed by: LEO Pharma Inc., Seven Giralda Farms, Madison, NJ 07940, USA. For more information call 1-877-494-4536.

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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