

INSTRUCTIONS FOR USE
PICATO® (Pih-KAY-toe)
(ingenol mebutate)
gel, 0.015%

This Instructions for Use contains information on how to apply Picato gel.

Be sure that you read, understand, and follow these Instructions for Use before you use Picato gel for the first time. Also read the Patient Information leaflet that comes with Picato gel.

Important Information You Need to Know Before Applying Picato gel:

- **For topical use only** (apply on top of skin)

- **Always use Picato gel exactly as your healthcare provider tells you.** Check with your healthcare provider or pharmacist if you are not sure.

- Only use **Picato gel, 0.015%** to treat actinic keratosis on your **face or scalp**.

- Apply Picato gel, 0.015% to the skin area to be treated **1** time each day for 3 days in a row. Use a new tube for each day of treatment.

- Avoid touching the treatment area or doing activities that cause a lot of sweating for 6 hours after applying Picato gel. After 6 hours you may wash the treatment area with a mild soap and water.

Do not:

- apply right after taking a shower or less than **2** hours before bedtime.
- **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 it. 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 the section of Patient Information leaflet section called “What are the possible side effects of Picato gel?”.
- **get Picato gel in, around, or near your lips and mouth.**

Applying Picato gel

Step 1. Open a new tube each time you use Picato gel.

Step 2. Remove cap from tube just before use. (See **Figure A**.)

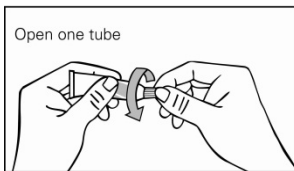


Figure A

Step 3. Squeeze the gel from the tube onto a fingertip. (See **Figure B**.) Only use enough gel needed to cover the affected area, as directed by your healthcare provider. One tube contains enough gel to cover a skin area of about 2 inches by 2 inches.

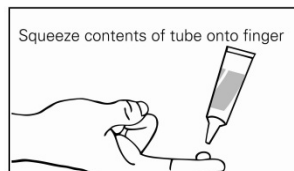


Figure B

Step 4. Spread the gel evenly over only the skin area to be treated. Do not get in, around or near the eyes, lips, and mouth. Allow the treated area to dry for 15 minutes. (See **Figure C.**)



Figure C

Step 5. Wash your hands right away after applying Picato[®] gel. (See **Figure D.**)

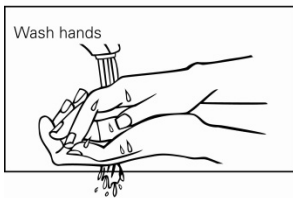


Figure D

Step 6. Safely throw away (dispose of) the tube after use.

Repeat the above steps for each day of treatment.

To help prevent 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.

Storing 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.

Disposing of Picato gel

- Safely throw away used Picato gel tubes in household trash.

For more information call: 1-877-494-4536.

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

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This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Revised: 2/2020

INSTRUCTIONS FOR USE
PICATO® (Pih-KAY-toe)
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gel, 0.05%

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Important Information You Need to Know Before Applying Picato gel:

- **For topical use only** (apply on top of skin)

- **Always use Picato gel exactly as your healthcare provider tells you.** Check with your healthcare provider or pharmacist if you are not sure.

- Only use **Picato gel, 0.05%** to treat actinic keratosis on your **body, arms, hands or legs.**

- Apply Picato gel, 0.05% to the skin area to be treated **1** time each day for 2 days in a row. Use a new tube for each day of treatment.

- Avoid touching the treatment area or doing activities that cause a lot of sweating for 6 hours after applying Picato gel. After 6 hours you may wash the treatment area with a mild soap and water.

Do not:

- apply right after taking a shower or less than **2** hours before bedtime.
- **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 it. 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 the section of Patient Information leaflet section called “What are the possible side effects of Picato gel?”.
- **get Picato gel in, around, or near your lips and mouth.**

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Step 1. Open a new tube each time you use Picato gel.

Step 2. Remove cap from tube just before use. (See **Figure A.**)

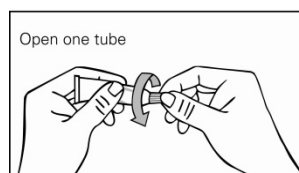


Figure A

Step 3. Squeeze the gel from the tube onto a fingertip. (See **Figure B.**) Only use enough gel needed to cover the affected area, as directed by your healthcare provider. One tube contains enough gel to cover a skin area of about 2 inches by 2 inches.

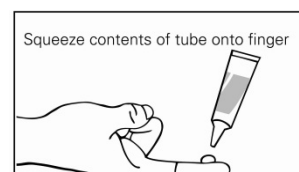


Figure B

Step 4. Spread the gel evenly over only the skin area to be treated. Do not get in, around or near the eyes, lips, and mouth. Allow the treated area to dry for 15 minutes. (See **Figure C.**)



Figure C

Step 5. Wash your hands right away after applying Picato® gel. (See **Figure D.**) If you are treating your hands you should only wash the fingertip which you used for applying the gel.

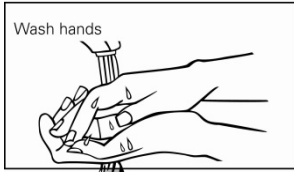


Figure D

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