

PART III: CONSUMER INFORMATION

^{Pr}PICATO® Ingenol mebutate gel

This leaflet is part III of a three-part "Product Monograph" published when Picato® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Picato®. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Picato® is used for the topical treatment of Actinic Keratosis.

Actinic Keratosis (AK) lesions are thick, hard, scaly patches on skin that has been damaged by too much sun (UV) exposure.

What it does:

Picato® gel contains ingenol mebutate which is thought to be toxic to cells and promote a local inflammatory response.

When it should not be used:

Do not use Picato® gel if you are allergic (hypersensitive) to ingenol mebutate or any of the ingredients in the gel.

What the medicinal ingredient is:

Picato® gel contains ingenol mebutate.

What the important nonmedicinal ingredients are:

Picato® gel contains isopropyl alcohol, hydroxyethyl cellulose, citric acid monohydrate, sodium citrate, benzyl alcohol and purified water.

What dosage forms it comes in:

Picato® is a clear, colourless gel available in 2 strengths.

Picato® gel 0.015 %: Each carton contains 3 unit dose tubes

Picato® gel 0.05 %: Each carton contains 2 unit dose tubes

WARNINGS AND PRECAUTIONS

- Do not apply the gel in, near, or around the eyes. Picato® gel is irritating to the eyes. If accidental application to the eye occurs, flush the area with plenty of water and seek medical care immediately
- Do not apply the gel on the inside of the nostrils, on the inside of the ears, on or near the mouth and lips, or on skin outside the treatment area as defined by your doctor.
- Do not apply Picato® 0.05% on the face or scalp, only use Picato® 0.015% on the face or scalp.
- Make sure that the skin has healed from the other treatments or surgery before applying Picato® gel.
- If Picato® gel is accidentally swallowed drink plenty of water and seek medical care immediately.

- Picato® gel has not been studied in patients under 18 years of age.

BEFORE you use Picato® gel talk to your doctor or pharmacist if you:

- Are pregnant or planning to become pregnant.
- Are breastfeeding.
- Have had other treatments for AK.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription medicines (such as vitamins, herbal remedies, etc.). It is not known if Picato® gel and other medicines can affect each other.

PROPER USE OF THIS MEDICATION

Always use Picato® gel exactly as prescribed by your doctor and only on the area(s) of skin to be treated. Use the correct Picato® gel on the correct skin area. Do not use Picato® gel 0.05% on the face or scalp.

Usual dose:

- For treatment of AK on the face or scalp, use one unit dose tube of 0.015% gel once daily for 3 days in a row.
- For treatment of AK on the body, arms, hands or legs, use one unit dose tube of 0.05% gel once daily for 2 days in a row.

Instructions for use:

- Open a new tube each time you use Picato® gel. Remove the cap from the tube just before using.
- Squeeze the contents from one tube onto your fingertip.
- One tube has enough gel to cover about a 25 cm² (5 cm x 5 cm) area of skin.
- Gently rub the gel over the affected skin area.
- To help prevent accidental transfer of Picato® gel to your eyes or other areas of your body:
 - Wash your hands immediately after applying Picato® gel. If you are treating your hands, you should wash only the fingertip you used for applying the gel.
 - Allow the area to dry for 15 minutes.
 - Do not wash or touch the treated area yourself or allow anyone to touch the treated skin for a period of 6 hours after applying Picato® gel.
 - Do not apply Picato® gel immediately after taking a shower or less than 2 hours before bedtime.
- After 6 hours you may wash the area with a mild soap and water.
- Do not cover the treated skin area with a bandage or other type of dressing after you have applied Picato® gel.

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thickened, and peeling skin. These reactions can start within one day of treatment and may get worse for up to one week after you have stopped using Picato®. These will usually get better within 2 weeks from when you started treatment on the face or scalp, and within 4 weeks from when you started treatment on body, arms, hands or legs. If these reactions do not improve, see your doctor.

Common side effects: pain, itching, skin irritation or infection at the treatment area, swelling around the eyes, and headache.

There have been reports of serious allergic reactions with the use of Picato® gel. Get medical help immediately if you have any of the following symptoms of a serious allergic reaction: swelling of the lips or tongue, trouble breathing or wheezing, chest tightness, dizziness or passing out.

There have been reports of serious chemical pinkeye and serious burn injuries to the eye caused by accidentally getting Picato® gel in the eyes. If you accidentally get Picato® gel in your eyes, flush them with large amounts of water and seek medical care immediately.

It is possible that you may experience lightening or darkening of your skin with the use of Picato® gel.

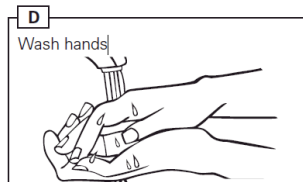
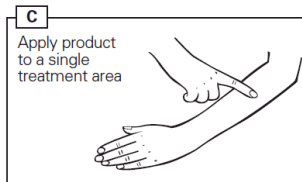
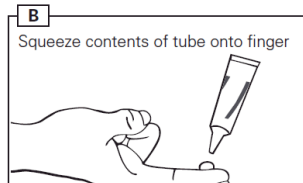
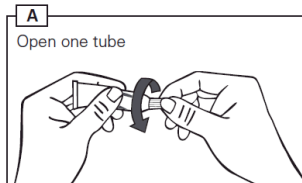
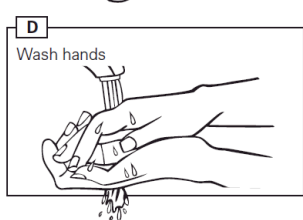
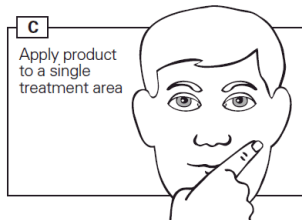
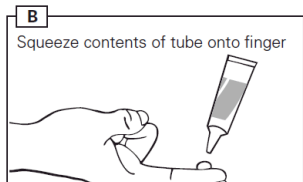
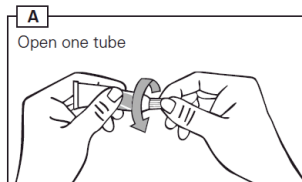
Talk to your Health Care Provider if you have questions about your treatment or side effects.

HOW TO STORE IT

Store Picato® gel in a refrigerator (2°C to 8°C).

Keep Picato® gel out of the reach of children and pets.

Do not use Picato® gel after the expiry date (EXP). Tubes should not be re-used once opened.



Overdose:

In case of drug overdose or accidental ingestion, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, contact your doctor.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects with Picato® include:

The most common side effects: local skin reactions at the treatment site. These include redness, flaking, scabbing and crusting, swelling, blister or ulcer, skin that becomes hard or

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.leo-pharma.com/canada or by contacting the sponsor, LEO Pharma Inc., at: 1-800-668-7234.

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