

Picato® gel, 0.05%

Ingenol (in' jen ol) mebutate (me bue' tate)

Consumer Medicine Information

Please read this leaflet carefully before you start your treatment.

Picato® gel, 0.05% is the brand name. The generic name of the active ingredient is ingenol mebutate.

Keep this leaflet.

You may want to read it again.

What is in this leaflet?

This leaflet answers some common questions about using the medicine Picato® gel, 0.05%. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Picato® gel against the benefits it is expected to have for you.

If you have any concerns about using Picato® gel talk to your doctor or pharmacist.

What Picato® gel, 0.05% is used for

Picato® gel, 0.05% is used as a topical treatment of solar keratoses (sun spots) on the body of adults.

Solar keratoses are thickened, scaly patches of skin caused by too much sun exposure. Solar keratoses are also known as actinic keratoses.

Picato® gel contains the active ingredient ingenol mebutate.

The ingenol mebutate in Picato® gel treats the lesions in the area where the gel is applied.

IT IS NOT RECOMMENDED THAT PICATO® GEL, 0.05% IS USED ON THE FACE OR SCALP – IT IS TOO STRONG.

Picato® gel, 0.05% is only available with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

This medicine is not addictive.

Before you use Picato® gel

When you must not use Picato® gel

Do not use Picato® gel if you are allergic to ingenol mebutate or any of the other ingredients listed at the end of this leaflet (see **Product description**).

Some of the symptoms of an allergic reaction include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or “hives” on the skin.

Do not use Picato® gel on broken skin

Do not use Picato® gel

- after the expiry date printed on the pack OR
- if the packaging is torn, doesn't look quite right or shows signs of tampering.

If any of these apply, return the medicine to your pharmacist for disposal.

If you are not sure whether you should start using Picato® gel talk to your doctor.

Before you start to use Picato® gel

Tell your doctor if you have a known allergy to Picato® gel, ingenol mebutate or any of the ingredients listed at the end of this leaflet.

Tell your doctor if you

- are pregnant or intend to become pregnant.
- are taking any other medicines
- currently have, or in the past have had, any other medical conditions.

Do not use Picato® gel on children.

Solar keratoses is not a condition that normally affects children. Safety and effectiveness of Picato® gel in those below 18 years of age has not been established.

If you have not told your doctor about any of the above, tell him/her before you start using this medicine.

Other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Your doctor and pharmacist have more information on medicines you should be careful with or avoid whilst using Picato® gel.

How to use Picato® gel, 0.05%

Follow carefully all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor or pharmacist for help.

How much Picato® gel, 0.05% to use

Each carton of Picato® gel, 0.05% contains 2 small tubes.

Each tube of Picato® gel, 0.05% contains a single dose. You should apply the contents of 1 tube to the area on your body containing the sun spot(s) / lesion(s).

Each tube of Picato® gel, 0.05% contains enough gel to cover an area of approximately 25cm² (e.g. 5cm x 5cm), which is approximately the area of the back of one hand. You should not put Picato® gel in areas where skin will cover the application site, such as under the arm or under the breast.

How to use Picato® gel, 0.05%

Apply Picato® gel, 0.05% only to treatment areas on the body. Do not apply to the face or scalp – it is too strong.

Use Picato® gel, 0.05% as follows:

- Squeeze the gel from the single use tube onto the fingertip and then spread it evenly over the treatment area
- Allow treatment area to dry for 15 minutes. Do not touch during this time.
- If applying to the hands, **wash only the fingertip you used to apply the gel after application.**
- If applying to other parts of the body, wash your hands with soap and water immediately after application.

- Do not wash the area of the body where Picato® gel, 0.05% was applied for at least 6 hours after application
- After this period the treatment area may be washed using mild soap and water.
- Picato® gel, 0.05% should not be applied immediately before or after taking a shower because the skin needs to be very dry before application
- Picato® gel, 0.05% should not be applied less than 2 hours before bedtime
- The area treated with Picato® gel, 0.05% should not be covered with occlusive bandages.

The full effects of Picato® gel, 0.05% are best assessed approximately 8 weeks after treatment.

How long to use Picato® gel

A treatment course lasts for 2 days.

Apply Picato® gel, 0.05% **once a day** for 2 days in a row.

If you forget to use Picato® gel

If you forget to apply the second tube of Picato® gel within 3 days of the first tube, apply the second tube when you remember. If it has been more than 3 days since you applied the first tube, do not apply the second tube. If this happens you should contact your doctor.

If you are not sure what to do, ask your doctor or pharmacist.

If you use too much or use it other than directed (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (Telephone 13 11 26 in Australia or 0800 764 766 in New Zealand) for advice, or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have used too much or swallowed some of

this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Picato® gel

Things you must do

While you are using Picato® gel you should protect the treated skin areas from sunlight and ultraviolet (UV) rays. This can be done by wearing a hat and covering the treated area with clothing before going outside. Sunscreens and moisturisers (non-medicated, non-irritant) can be applied to the treated area once treatment is completed and if the skin is not broken.

If you are going to start any new medicine, tell your doctor and pharmacist that you are using Picato® gel.

If you become pregnant while using Picato® gel, tell your doctor immediately.

If you experience an allergic reaction whilst you are using Picato® gel, stop using it, and immediately seek medical attention.

Monitor your skin and watch for any new scaly red patches, open sores, elevated or wart-like growths within the treatment area. If you notice any of these, tell your doctor immediately.

Keep all appointments with your doctor so that your progress can be checked.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not use more than the recommended daily dose (see How to use Picato® gel, 0.05%).

DO NOT APPLY PICATO® GEL TO OR NEAR YOUR EYE AREA.

Avoid contact with, or accidental transfer to, the eye area during or after treatment.

If it gets into your eyes or your eye area, flush with plenty of water then consult your doctor immediately.

Side effects

As with all medicines, Picato® gel can cause some side effects.

The most common effects are expected and show that the treatment is working.

The expected effects at the application site include:

- Skin reddening
- Skin flaking or scaling
- Mild swelling
- Crusting or Scabbing
- Blistering

Swelling at the application site may extend to the eye area.

Side effects not listed above may also occur in some people. These less common side effects include:

- Pain
- Itching
- Irritation
- Ulceration of the treatment site.

All these effects usually clear within 4 weeks. If the effects continue for longer you should talk to your doctor.

Tell your doctor or pharmacist if you notice the following side effects:

- Ulcers forming
- Skin weeping
- Swelling of the eye area
- You think the application site has become infected.

You should also tell your doctor or pharmacist if you have any additional unpleasant effects while you are using Picato® gel.

After using Picato® gel

Keep Picato® gel in the box in the refrigerator until required.

Storage

STORE PICATO® GEL IN THE REFRIGERATOR AT 2-8°C.

Picato® gel can spend a short time outside of the refrigerator if the temperature is below 30°C. This will allow you time to get Picato® gel home from the pharmacy and into the refrigerator.

Periods of storage outside of the refrigerator may reduce the effectiveness of Picato® gel.

Store Picato® gel where children cannot reach it.

Disposal

Ask your pharmacist what to do with Picato® gel that is left over if:

- your doctor tells you to stop using Picato® gel ,
or
- the expiry date has passed

Product description

What it looks like

Picato® gel is a clear, colourless gel.

Ingredients

Picato® gel contains the active ingredient ingenol mebutate.

It also contains:

- isopropyl alcohol,
- hydroxyethylcellulose,
- citric acid monohydrate,
- sodium citrate,
- benzyl alcohol

The Australian Registration Number is AUST R 190113

This is not all the information available on Picato® gel, 0.05%. If you have any more questions or are

unsure about anything, ask your doctor or pharmacist.

Supplier

Picato® gel is supplied in Australia by:

LEO Pharma Pty Ltd, Level 3,
Tower 1, 25 Montpelier Road,
Bowen Hills, QLD 4006,
AUSTRALIA

Picato® gel is supplied in New Zealand by:

LEO Pharma Ltd, Level 31, Vero
Centre, 48 Shortland St, Auckland,
NEW ZEALAND.

Contact details:

Australia Toll free no: 1800 991
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New Zealand Toll free no: 0800
497 456

Email: medical-info.au@leo-pharma.com

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