Picato® gel, 0.015%

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

Consumer Medicine Information (CMI)

Please read this leaflet carefully before you start your treatment.

Picato® gel, 0.015% 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, 0.015%. 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, 0.015% is used for

Picato® gel, 0.015% is used as a topical treatment of solar keratoses (sun spots) on the face and scalp 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.

USE PICATO® GEL 0.015% ON YOUR FACE AND SCALP

IT IS NOT RECOMMENDED THAT PICATO® GEL, 0.015% IS USED ON OTHER PARTS OF YOUR BODY

Picato® gel 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

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, 0.015%

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, 0.015% to use

Each carton of Picato® gel, 0.015% contains 3 small tubes.

Each tube of Picato® gel, 0.015% contains a single dose. You should apply the contents of 1 tube to the area on your face or scalp containing the sun spot (s) / lesion(s).

Each tube of Picato® gel, 0.015% contains enough gel to cover an area of approximately 25cm² (e.g. 5cm x 5cm). However, avoid getting Picato® gel close to the eye area, nostrils and mouth. If the lesion is near the eye area, nostrils or mouth you may need to apply Picato® gel to a smaller treatment area.

How to use Picato® gel, 0.015%

Apply Picato® gel, 0.015% only to treatment areas on the face or scalp.

Use Picato® gel, 0.015% 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.
- Wash your fingertip with soap and water immediately after application.
- Do not wash the area of the body where Picato® gel, 0.015% 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, 0.015% should not be applied immediately before or after taking a shower as the skin needs to be very dry before application
- Picato® gel, 0.015% should not be applied less than 2 hours before bedtime
- The area treated with Picato® gel, 0.015% should not be covered with occlusive bandages.

Things you must do

While you are using Picato® gel

The expected effects at the application site include:
- Skin reddening
- Skin flaking or scaling
- Mild swelling
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 2 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
- the expiry date has passed

This leaflet was revised in May 2017.

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 190122

This is not all the information available on Picato® gel, 0.015%. 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.

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