HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PICATO® gel safely and effectively. See full prescribing information for PICATO® gel.

PICATO® (ingenol mebutate) gel, 0.015% for topical use
Initial U.S. Approval: 2012

INDICATIONS AND USAGE
Picato® gel is an inducer of cell death indicated for the topical treatment of actinic keratosis. (1)

DOSAGE AND ADMINISTRATION
- For topical use only; not for oral, ophthalmic, or intravaginal use. (2)
- Actinic keratosis on the face and scalp: Apply Picato® gel, 0.015% to the affected area once daily for 3 consecutive days. (2)
- Actinic keratosis on the trunk and extremities: Apply Picato® gel, 0.05% to the affected area once daily for 2 consecutive days. (2)

DOSE FORMS AND STRENGTHS
Gel containing ingenol mebutate, 0.015% or 0.05% (3)

CONTRAINDICATIONS
None. (4)

WARNINGS AND PRECAUTIONS
- Eye disorders, including severe eye pain, eyelid edema, eyelid ptosis, periorbital edema can occur after exposure. Avoid contact with the periorcular area. If accidental exposure occurs, flush eyes with water and seek medical care. (5.1)
- Local skin reactions can occur including severe reactions (e.g., vesiculation/pustulation, erosion/ulceration). Administration of Picato® gel is not recommended until skin is healed from any previous drug or surgical treatment. (5.2)

ADVERSE REACTIONS
The most common adverse reactions (≥2%) are local skin reactions, application site pain, application site pruritus, application site irritation, application site infection, periorbital edema, nasopharyngitis and headache. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact LEO Pharma Inc. at 1-877-494-4536 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 01/2012

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2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
6 ADVERSE REACTIONS
7 CLINICAL PHARMACOLOGY
8 USE IN SPECIFIC POPULATIONS
9 OVERDOSAGE
10 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
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13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
14.1 Actinic Keratosis of the Face and Scalp
14.2 Actinic Keratosis of the Trunk and Extremities
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the Full Prescribing Information are not listed.
FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
Picato® gel is indicated for the topical treatment of actinic keratosis.

2 DOSAGE AND ADMINISTRATION
For topical use only; Picato® gel is not for oral, ophthalmic, or intravaginal use.

For the treatment of actinic keratosis on the face and scalp Picato® gel, 0.015% should be applied to the affected area once daily for 3 consecutive days.

For the treatment of actinic keratosis on the trunk and extremities Picato® gel, 0.05% should be applied to the affected area once daily for 2 consecutive days.

Picato® gel may be applied to the affected area, up to one contiguous skin area of approximately 25 cm² (e.g., 5 cm x 5 cm) using one unit dose tube. After spreading evenly over the treatment area, the gel should be allowed to dry for 15 minutes. Patients should wash their hands immediately after applying Picato® gel and take care not to transfer the applied drug to other areas, including the eye. Patients should avoid washing and touching the treated area for a period of 6 hours after application of Picato® gel. Following this time, patients may wash the area with a mild soap.

3 DOSAGE FORMS AND STRENGTHS
Gel, 0.015% or 0.05%, in a clear colorless gel base.

4 CONTRAINDICATIONS
None.

5 WARNINGS AND PRECAUTIONS
5.1 Eye Exposure
Eye disorders, including severe eye pain, eyelid edema, eyelid ptosis, periorbital edema can occur after exposure [see Adverse Reactions (6)]. Patients should wash hands well after applying Picato® gel, and avoid transfer of the drug to the periorcular area during and after application [see Patient Counseling Information (17)]. If accidental exposure occurs, the area should be flushed with water and the patient should seek medical care as soon as possible [see Adverse Reactions (6)].

5.2 Local Skin Reactions
Severe skin reactions in the treated area, including erythema, crusting, swelling, vesiculation/postulation, and erosion/ulceration, can occur after topical application of Picato® gel [see Adverse Reactions (6)]. Administration of Picato® gel is not recommended until the skin is healed from any previous drug or surgical treatment.

6 ADVERSE REACTIONS

Reference ID: 3075879
6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The data described below reflect exposure to Picato® gel in 499 subjects with actinic keratosis, including 274 subjects exposed to Picato® gel field treatment (skin area of 25 cm² in the face or scalp regions) at a concentration of 0.015% once daily for 3 consecutive days, and 225 subjects exposed to Picato® gel field treatment (skin area of 25 cm² in the trunk or extremities regions) at a concentration of 0.05% once daily for 2 consecutive days.

Local skin reactions, including erythema, flaking/scaling, crusting, swelling, vesiculation/pustulation, and erosion/ulceration were assessed within the selected treatment area and graded by the investigator on a scale of 0 to 4. A grade of 0 represented no reaction present in the treated area, and a grade of 4 indicated a marked and severe skin reaction that extended beyond the treated area.

Table 1 Investigator Assessment of Maximal Local Skin Reactions in the Treatment Area during the 57 Days Post Treatment Period (face/scalp trials)

<table>
<thead>
<tr>
<th>Face and Scalp (n=545)</th>
<th>Picato® gel, 0.015% once daily for 3 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin reactions</td>
<td>Any Grade&lt;sup&gt;a&lt;/sup&gt; &gt; Baseline</td>
</tr>
<tr>
<td></td>
<td>Picato® gel (n=274)</td>
</tr>
<tr>
<td>Erythema</td>
<td>258 (94%)</td>
</tr>
<tr>
<td>Flaking/Scaling</td>
<td>233 (85%)</td>
</tr>
<tr>
<td>Crusting</td>
<td>220 (80%)</td>
</tr>
<tr>
<td>Swelling</td>
<td>217 (79%)</td>
</tr>
<tr>
<td>Vesiculation/Pustulation</td>
<td>154 (56%)</td>
</tr>
<tr>
<td>Erosion/Ulceration</td>
<td>87 (32%)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Mild (grade 1), Moderate (grade 2-3) or Severe (grade 4).
Table 2 Investigator Assessment of Maximal Local Skin Reactions in the Treatment Area during the 57 Days Post Treatment Period (trunk/extremities trials)

<table>
<thead>
<tr>
<th>Skin reactions</th>
<th>Any Grade&lt;sup&gt;a&lt;/sup&gt; &gt; Baseline</th>
<th>Grade 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Picato&lt;sup&gt;®&lt;/sup&gt; gel (n=225)</td>
<td>Vehicle (n=232)</td>
</tr>
<tr>
<td>Erythema</td>
<td>207 (92%)</td>
<td>43 (19%)</td>
</tr>
<tr>
<td>Flaking/Scaling</td>
<td>203 (90%)</td>
<td>44 (19%)</td>
</tr>
<tr>
<td>Crusting</td>
<td>167 (74%)</td>
<td>23 (10%)</td>
</tr>
<tr>
<td>Swelling</td>
<td>143 (64%)</td>
<td>13 (6%)</td>
</tr>
<tr>
<td>Vesiculation/Pustulation</td>
<td>98 (44%)</td>
<td>2 (1%)</td>
</tr>
<tr>
<td>Erosion/Ulceration</td>
<td>58 (26%)</td>
<td>6 (3%)</td>
</tr>
</tbody>
</table>

<sup>a</sup>Mild (grade 1), Moderate (grade 2-3) or Severe (grade 4).

Local skin reactions typically occurred within 1 day of treatment initiation, peaked in intensity up to 1 week following completion of treatment, and resolved within 2 weeks for areas treated on the face and scalp, and within 4 weeks for areas treated on the trunk and extremities.

Adverse reactions that occurred in ≥2% of subjects treated with Picato<sup>®</sup> gel and at a higher frequency than the vehicle are presented in Table 3 and Table 4.

Table 3 Adverse reactions occurring in ≥2% of subjects treated with Picato<sup>®</sup> gel and at higher frequency than vehicle (face/scalp trials)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Face/Scalp</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Picato&lt;sup&gt;®&lt;/sup&gt; gel, 0.015% (N=274)</td>
</tr>
<tr>
<td>Application Site Pain</td>
<td>42 (15%)</td>
</tr>
<tr>
<td>Application Site Pruritus</td>
<td>22 (8%)</td>
</tr>
<tr>
<td>Application Site Infection</td>
<td>7 (3%)</td>
</tr>
<tr>
<td>Periorbital Edema</td>
<td>7 (3%)</td>
</tr>
<tr>
<td>Headache</td>
<td>6 (2%)</td>
</tr>
</tbody>
</table>
Table 4 Adverse reactions occurring in ≥ 2% of subjects treated with Picato® gel and at higher frequency than vehicle (trunk/extremities trials)

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Trunk/Extremities</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Picato® gel, 0.05% (N=225)</td>
</tr>
<tr>
<td>Application Site Pruritus</td>
<td>18 (8%)</td>
</tr>
<tr>
<td>Application Site Irritation</td>
<td>8 (4%)</td>
</tr>
<tr>
<td>Nasopharyngitis</td>
<td>4 (2%)</td>
</tr>
<tr>
<td>Application Site Pain</td>
<td>5 (2%)</td>
</tr>
</tbody>
</table>

Less common adverse reactions in subjects treated with Picato® included: eyelid edema, eye pain, conjunctivitis.

A total of 108 subjects treated with Picato® gel on the face/scalp and 38 subjects treated on the trunk/extremities were followed for 12 months. Results from these studies did not change the safety profile of Picato® gel.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Category C

There are no adequate and well-controlled studies of Picato® gel in pregnant women. Picato® gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Systemic embryofetal development studies were conducted with ingenol mebutate in rats and rabbits. Intravenous doses of 1.5, 3, and 5 µg/kg/day (9, 18, and 30 µg/m²/day) ingenol mebutate were administered during the period of organogenesis (gestational days 6 – 16) to pregnant female rats. No treatment related effects on embryofetal toxicity or teratogenicity were noted at doses up to 5 µg/kg/day (30 µg/m²/day). Intravenous doses of 1, 2, and 4 µg/kg/day (12, 24, and 48 µg/m²/day) ingenol mebutate were administered during the period of organogenesis (gestational days 6 – 18) to pregnant female rabbits. An increase in embryo-fetal mortality was noted at 4 µg/kg/day (48 µg/m²/day). An increased incidence of fetal visceral and skeletal variations was noted in all three ingenol mebutate dose groups. The clinical relevance of these findings is unclear since systemic exposure of ingenol mebutate was not detected in subjects with actinic keratosis treated with Picato® gel, 0.05% applied to a 100 cm² treatment area [see Clinical Pharmacology (12.3)].

8.4 Pediatric Use
Actinic keratosis is not a condition generally seen within the pediatric population.

The safety and effectiveness of Picato® gel for actinic keratosis in patients less than 18 years of age have not been established.
8.5 Geriatric Use
Of the 1165 subjects treated with Picato® gel in the clinical trials, 56% were 65 years and older and, 21% were 75 years and older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects.

10 OVERDOSAGE
Topical overdosing of Picato® gel could result in an increased incidence of local skin reactions.

11 DESCRIPTION
Picato® (ingenol mebutate) gel, 0.015% or 0.05% is a clear colorless gel for topical administration, which contains the active substance ingenol mebutate, an inducer of cell death.

The chemical name of ingenol mebutate is:
2-Butenoic acid, 2-methyl-,(1aR,2S,5R,5aS,6S,8aS,9R,10aR)-1a,2,5,5a,6,9,10,10a-octahydro-5,5a-dihydroxy-4-(hydroxymethyl)-1,1,7,9-tetramethyl-11-oxo-1H-2,8a-methanocyclopenta [a]cyclopropa[e]cyclodecen-6-yl ester, (2Z) - or (1aR,2S,5R,5aS,6S,8aS,9R,10aR)-5,5a-dihydroxy-4-(hydroxymethyl)-1,1,7,9-tetramethyl-11-oxo-1a,2,5,5a,6,9,10,10a-octahydro-1H 2,8a-methanocyclopenta[a]cyclopropa[e]cyclodecen-6-yl (2Z) 2 methylbut-2-enoate.

The molecular formula is C25H34O6 and molecular weight is 430.5. Ingenol mebutate is represented by the following structural formula:

![Structural formula of ingenol mebutate]

Ingenol mebutate is a white to pale yellow crystalline powder.

Picato® gel, 0.015% and 0.05% contains 150 mcg and 500 mcg of ingenol mebutate, respectively in each gram of gel consisting of isopropyl alcohol, hydroxyethyl cellulose, citric acid monohydrate, sodium citrate, benzyl alcohol and purified water.

Picato® gel is clear colorless gel and supplied in unit dose laminate tubes, for single use, containing a nominal fill weight of 0.47 g, with a deliverable weight of 0.25 g. The tubes should be discarded after single use.

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
The mechanism of action by which Picato® gel induces cell death in treating AK lesions is unknown.
12.2 Pharmacodynamics
The pharmacodynamics of Picato® gel is unknown.

12.3 Pharmacokinetics
Absorption
The systemic exposure to Picato® gel, 0.05% was assessed in two studies in a total of 16 subjects with AK, following application of approximately 1 g of Picato® gel, 0.05% to an area of 100 cm² of the dorsal forearm once daily for two consecutive days. In these studies, the blood levels of ingenol mebutate and two of its metabolites (acyl isomers of ingenol mebutate) were measured. Blood levels of ingenol mebutate and the two metabolites were below the lower limit of quantification (0.1 ng/mL) in all the blood samples of the subjects evaluated.

Drug Interactions
In vitro studies demonstrated that [³H]-ingenol mebutate undergoes extensive metabolism in human hepatocytes.

In vitro studies to assess the potential of ingenol mebutate to inhibit or induce human cytochrome P450 (CYP) enzymes demonstrated that ingenol mebutate does not inhibit CYP 1A2, 2A6, 2B6, 2C8, 2C9, 2C19, 2D6, 2E1, and 3A4 or induce CYP 1A2, 2C9, and 3A4. The estimated expected systemic exposure (< 0.1 ng/mL) following topical application of Picato® gel, 0.05% to AK subjects in the pharmacokinetic studies described above is negligible compared to the concentrations of ingenol mebutate evaluated in the in vitro studies.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term animal studies have not been performed to evaluate the carcinogenic potential of Picato® gel or ingenol mebutate. The effects of ingenol mebutate on fertility have not been evaluated.

Ingenol mebutate was negative in the Ames test, in vitro mouse lymphoma assay, and in vivo rat micronucleus test, but positive in the Syrian hamster embryo (SHE) cell transformation assay.

14 CLINICAL STUDIES
14.1 Actinic Keratosis of the Face and Scalp
In two double-blind, vehicle-controlled, clinical trials, 547 adult subjects with AK on the face or scalp were randomized to treatment with either Picato® gel, 0.015% or vehicle gel for 3 consecutive days, followed by an 8 week follow-up period. The studies enrolled subjects with 4 to 8 clinically typical, visible, discrete AK lesions within a 25 cm² contiguous treatment area. Hypertrophic and hyperkeratotic lesions were excluded from treatment. On each scheduled dosing day, the study gel was applied to the entire treatment area. A total of 536 subjects (98%) completed these studies. Study subjects ranged from 34 to 89 years of age (mean 64 years) and 94% had Fitzpatrick skin type I, II, or III. Approximately 85% of subjects were male, and all Picato®-treated subjects were Caucasian.
Efficacy was assessed at Day 57. Complete clearance rate was defined as the proportion of subjects with no (zero) clinically visible AK lesions in the treatment area. Partial clearance rate was defined as the proportion of subjects with 75% or greater reduction in the number of AK lesions at baseline in the selected treatment area. Table 5 presents the efficacy results for each trial.

Table 5 Number and Percent of Subjects Achieving Complete and Partial Clearance at Day 57 in Each Trial

<table>
<thead>
<tr>
<th></th>
<th>Study 1</th>
<th></th>
<th>Study 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Picato® gel, 0.015% (N=135)</td>
<td>Vehicle (N=134)</td>
<td>Picato® gel, 0.015% (N=142)</td>
</tr>
<tr>
<td>Complete Clearance Rate</td>
<td>50 (37%)</td>
<td>3 (2%)</td>
<td>67 (47%)</td>
</tr>
<tr>
<td>Partial Clearance Rate (≥ 75%)</td>
<td>81 (60%)</td>
<td>9 (7%)</td>
<td>96 (68%)</td>
</tr>
</tbody>
</table>

Table 6 presents the response rates by anatomical location for each trial.

Table 6 Number and Percent of Subjects Achieving Complete Clearance at Day 57 by Anatomical Location and by Trial

<table>
<thead>
<tr>
<th></th>
<th>Study 1</th>
<th></th>
<th>Study 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Picato® gel, 0.015% (N=135)</td>
<td>Vehicle (N=134)</td>
<td>Picato® gel, 0.015% (N=142)</td>
</tr>
<tr>
<td>Scalp</td>
<td>4/26 (15%)</td>
<td>0/25 (0%)</td>
<td>9/31 (29%)</td>
</tr>
<tr>
<td>Face</td>
<td>46/109 (42%)</td>
<td>3/109 (2%)</td>
<td>58/111 (52%)</td>
</tr>
</tbody>
</table>

Subjects who achieved complete clearance at Day 57 in Study 1 and Study 2 entered a 12-month follow-up period. Based on 108 Picato® gel-treated subjects who achieved complete clearance in Study 1 and Study 2, the recurrence rate at 12 months was 54% where recurrence was defined as the percentage of subjects with any identified AK lesion in the previously treated area who achieved complete clearance at Day 57.

14.2 Actinic Keratosis of the Trunk and Extremities

In two double-blind, vehicle-controlled clinical trials, 458 adult subjects with AK on the trunk or extremities were randomized to treatment with either Picato® gel, 0.05% or vehicle gel for 2 consecutive days, followed by an 8 week follow-up period. The studies enrolled subjects with 4 to 8 clinically typical, visible, discrete AK lesions within a 25 cm² contiguous treatment area. Hypertrophic and hyperkeratotic lesions were excluded from treatment. On each scheduled dosing day, the study gel was applied to the entire treatment area. A total of 447 subjects (98%) completed these studies. Study subjects ranged from 34 to 89 years of age (mean 66 years) and 94% had Fitzpatrick skin type I, II, or III. Approximately 62% of subjects were male, and all Picato®-treated subjects were Caucasian.

Efficacy was assessed at Day 57. Complete clearance rate was defined as the proportion of subjects with no (zero) clinically visible AK lesions in the treatment area. The partial clearance
rate was defined as the proportion of subjects with 75% or greater reduction in the number of AK lesions at baseline in the selected treatment area. Table 7 presents the efficacy results for each study.

Table 7 Number and Percent of Subjects Achieving Complete and Partial Clearance at Day 57 in Each Trial

<table>
<thead>
<tr>
<th></th>
<th>Study 3</th>
<th></th>
<th>Study 4</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Picato® gel, 0.05% (N=126)</td>
<td>Vehicle (N=129)</td>
<td>Picato® gel, 0.05% (N=100)</td>
<td>Vehicle (N=103)</td>
</tr>
<tr>
<td>Complete Clearance Rate</td>
<td>35 (28%)</td>
<td>6 (5%)</td>
<td>42 (42%)</td>
<td>5 (5%)</td>
</tr>
<tr>
<td>Partial Clearance Rate (≥ 75%)</td>
<td>56 (44 %)</td>
<td>9 (7 %)</td>
<td>55 (55 %)</td>
<td>7 (7 %)</td>
</tr>
</tbody>
</table>

Table 8 presents the response rates by anatomical location for each study.

Table 8 Number and Percent of Subjects Achieving Complete Clearance at Day 57 by Anatomical Location and by Trial

<table>
<thead>
<tr>
<th></th>
<th>Study 3</th>
<th></th>
<th>Study 4</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Picato® gel, 0.05% (N=126)</td>
<td>Vehicle (N=129)</td>
<td>Picato® gel, 0.05% (N=100)</td>
<td>Vehicle (N=103)</td>
</tr>
<tr>
<td>Arm</td>
<td>22/84 (26 %)</td>
<td>4/82 (5 %)</td>
<td>27/59 (46 %)</td>
<td>3/67 (5 %)</td>
</tr>
<tr>
<td>Back of Hand</td>
<td>4/25 (16 %)</td>
<td>0/29 (0%)</td>
<td>6/28 (21 %)</td>
<td>0/27 (0 %)</td>
</tr>
<tr>
<td>Chest</td>
<td>8/9 (89 %)</td>
<td>1/8 (13 %)</td>
<td>3/5 (60 %)</td>
<td>1/3 (33 %)</td>
</tr>
<tr>
<td>Othera</td>
<td>1/8 (13 %)</td>
<td>1/10 (10 %)</td>
<td>6/8 (75 %)</td>
<td>1/6 (17 %)</td>
</tr>
</tbody>
</table>

*aOther includes shoulder, back, leg.

Subjects who achieved complete clearance at Day 57 in Study 4 entered a 12-month follow-up period. Based on 38 Picato® gel-treated subjects who achieved complete clearance in Study 4, the recurrence rate at 12 months was 50% where recurrence was defined as the percentage of subjects with any identified AK lesion in the previously treated area who achieved complete clearance at Day 57.

16 HOW SUPPLIED/STORAGE AND HANDLING

Picato® gel is a clear colorless gel and is supplied in unit dose laminate tubes containing a nominal fill weight of 0.47 g, with a deliverable weight of 0.25 g. The tubes should be discarded after single use.

Picato® gel is available in 2 dosage strengths: 0.015% and 0.05%.

<table>
<thead>
<tr>
<th>Dosage Strength</th>
<th>Number of unit dose tubes per carton</th>
<th>NDC#</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.015 %</td>
<td>3</td>
<td>50222-502-47</td>
</tr>
<tr>
<td>0.05 %</td>
<td>2</td>
<td>50222-503-47</td>
</tr>
</tbody>
</table>
Store Picato® gel in a refrigerator at 36ºF – 46ºF (2ºC – 8ºC); excursions permitted between 32ºF – 59ºF (0ºC – 15ºC) (see USP for controlled cold temperature). Protect from freezing.

17 PATIENT COUNSELING INFORMATION
“See FDA-approved patient labeling (Patient Information and Instructions for Use)”

Picato® gel should be used as directed by a physician.

Picato® gel is for external use only. Advise patients to avoid contact with the eyes. Inform patients that treatment with Picato® gel may lead to local skin reactions [see Warnings and Precautions (5)].

Patients should avoid inadvertent transfer of Picato® gel to other areas, or to another person. Instruct patients to:
• allow the treated area to dry for 15 minutes after application.
• avoid washing and touching the treated area, or participating in activities that cause excessive sweating, for 6 hours after treatment. Following this time, patients may wash the area with a mild soap.
• keep out of the reach of children.