



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Picato®

Common Name: Ingenol mebutate

PDL Category: Topical Antineoplastics

| <u>Comparable Products</u> | <u>Preferred Drug List Status</u> |
|----------------------------|-----------------------------------|
| Aldara™ | Preferred |
| Efudex® | Preferred |

Summary

Indications and Usage: Indicated for the topical treatment of actinic ketatosis (AK).¹

Mechanism of Action: Inducer of cell death. Exact mechanism of action is unknown. ¹

Dosage Forms: Gel: 0.015%, 0.05%

Recommended Dosage: Actinic keratosis on the face and scalp: Apply Picato® gel, 0.015% to the affected area once daily for 3 consecutive days. Actinic keratosis on the trunk and extremities: Apply Picato® gel, 0.05% to the affected area once daily for 2 consecutive days. ¹

Common Adverse Drug Reactions: Local skin reactions, application site pain, application site pruritus, application site irritation, application site infection, periorbital edema, nasopharyngitis and headache.¹

Contraindications: None.¹

Manufacturer: LEO Pharma, Inc.

Analysis: Picato® is indicated for the topical treatment of AK. Four double-blind, vehicle-controlled clinical trials were used to gain FDA approval. Patients in two clinical trials involving AK on the face or scalp were randomized to treatment with Picato® gel, 0.015% or vehicle gel for 3 consecutive days with an 8 week follow-up period. Complete clearance rate was 37% and 47% in the two trials. The recurrence rate for the complete responders at 12 months was 54%. Patients in two clinical trials involving AK on the trunk or extremities were randomized to treatment with Picato® gel, 0.05% or vehicle gel for 2 consecutive days with an 8 week follow-up period. Complete clearance rate was 28% and 42% in the two trials. The recurrence rate for the complete responders at 12 months was 50%. Preferred alternatives appear on the Preferred Drug List which have similar clinical efficacy and are more cost effective. Therefore, it is recommended that Picato® be added to the Preferred Drug List as a non-preferred drug.

IME Recommendation:

| | |
|---|---|
| <input type="checkbox"/> Preferred Drug | <input type="checkbox"/> Recommended Drug |
| <input checked="" type="checkbox"/> Non-Preferred Drug | <input type="checkbox"/> Non-Recommended Drug |
| <input type="checkbox"/> Preferred Drug with Conditions | |

1. Picato® [package insert]. Parsippany, NJ: LEO Pharma, Inc.; 2012.