Important Safety information for ALDARA (imiquimod) Cream, 5%

Indication
ALDARA Cream is indicated for the topical treatment of:

- Clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses (AKs) on the face or scalp in immunocompetent adults
- Biopsy-confirmed, primary superficial basal cell carcinoma (sBCC) in immunocompetent adults; maximum tumor diameter of 2.0 cm on trunk, neck, or extremities (excluding hands and feet), only when surgical methods are medically less appropriate and patient follow-up can be reasonably assured
- External genital and perianal warts/condyloma acuminata in patients 12 years or older

Limitations of Use: Efficacy was not demonstrated for molluscum contagiosum in children aged 2–12.

Important Safety Information
For topical use only. ALDARA is not for oral, ophthalmic, or intravaginal use.

Warnings

- Intense local inflammatory reactions can occur (e.g., skin weeping, erosion). Dosing interruption may be required.
- Severe local inflammatory reactions of the female external genitalia can lead to severe vulvar swelling, which can lead to urinary retention; dosing should be interrupted or discontinued.
- Flu-like systemic signs and symptoms including malaise, fever, nausea, myalgias, and rigors may occur. Dosing interruption may be required.
- Avoid exposure to sunlight and sunlamps. Wear sunscreen daily.
- Safety and efficacy have not been established for repeat treatment to the same area for AK.
- ALDARA is not recommended for treatment of BCC subtypes other than the superficial variant (sBCC).
- Treatment of urethral, intravaginal, cervical, rectal, or intra-anal viral disease is not recommended.

Unevaluated Populations The safety and efficacy of ALDARA have not been established in immunosuppressed patients, patients with Basal Cell Nevus Syndrome or Xeroderma Pigmentosum. It should be used with caution in patients with pre-existing autoimmune conditions.

Pregnancy/Nursing/Pediatrics ALDARA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Caution should be exercised when ALDARA is administered to nursing women. The safety and efficacy of ALDARA for AK or sBCC in patients less than 18 years of age have not been established. Safety and efficacy in patients with external genital/perianal warts below the age of 12 years have not been established.

Adverse Reactions The most common adverse reactions (incidence ≥28%) are application site reactions or local skin reactions: itching, burning, erythema, flaking/scaling/dryness, scabbing/crusting, edema, induration, excoriation, erosion, and ulceration. Other reported reactions (≥1%) include fatigue, fever and headache.

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please **click here** for full Prescribing Information.

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