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Retin-A Cream and Gel (tretinoin) - Drug Summary

Valeant Pharmaceuticals North America LLC

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Retin-A (tretinoin)

COMMON BRAND NAMES

Retin-A Micro, Retin-A

THERAPEUTIC CLASS

Retinoid

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Acne Vulgaris

Apply qpm/qhs to the skin where acne lesions appear, using enough to cover the entire affected area in a thin layer

PEDIATRIC DOSAGE & INDICATIONS

Acne Vulgaris

≥12 Years:
Retin-A Micro:
Apply qpm to the skin where acne lesions appear, using enough to cover the entire affected area in a thin layer

ADMINISTRATION

Topical route

Thoroughly cleanse the areas to be treated before applying the medication. To help limit skin irritation, wash treated skin gently, using a mild, non-medicated soap, and pat it dry; avoid washing treated skin too often or scrubbing hard when washing.
Keep away from eyes, mouth, paranasal creases of the nose, and mucous membranes.
Patients treated w/ therapy may use cosmetics.

HOW SUPPLIED

(Retin-A) Cre: 0.025%, 0.05%, 0.1% [20g, 45g]; **Gel:** 0.01%, 0.025% [15g, 45g]; **(Retin-A Micro) Gel:** 0.04%, 0.1% [20g, 45g, 50g], 0.08% [50g]

WARNINGS/PRECAUTIONS

Severe irritation on eczematous skin reported; use caution in patients w/ this condition. If the degree of local irritation warrants, temporarily reduce the amount/frequency of application, d/c use temporarily, or d/c use all together. D/C therapy if a reaction suggesting sensitivity or chemical irritation occurs. Avoid or minimize unprotected exposure to sunlight, including sunlamps (UV light); avoid use w/ sunburn until fully recovered. Caution in patients who may be required to have considerable sun exposure and those w/ inherent sensitivity to the sun. Use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided. Weather extremes (eg, cold, wind) may irritate skin. An apparent exacerbation of inflammatory lesions may occur during early weeks of therapy. A transitory feeling of warmth or slight stinging may be noted on application. **Retin-A:** May induce severe local erythema and peeling at application site. Gels are flammable. **Retin-A Micro:** Skin may become excessively dry, red, swollen, or blistered; apply topical moisturizer if dryness is bothersome.

ADVERSE REACTIONS

Skin irritation/burning, erythema, dermatitis, hyper/hypopigmentation.

DRUG INTERACTIONS

Caution w/ topical medications, medicated/abrasive soaps and cleansers, products w/ strong drying effect, and products w/ high concentrations of alcohol, astringents, limes, or spices. Caution w/ medications that cause photosensitivity. **Retin-A/Retin-A Micro 0.04%, 0.1%:** Caution w/ preparations containing sulfur, resorcinol, or salicylic acid; allow effects of these agents to subside before initiation of treatment. **Retin-A Micro 0.04%, 0.1%:** Caution w/ OTC acne preparations containing benzoyl peroxide.

PREGNANCY AND LACTATION

Pregnancy: Category C.
Lactation: Caution in nursing.

MECHANISM OF ACTION

Retinoid; exact mode of action not established. Current evidence suggests that topical tretinoin decreases cohesiveness of follicular epithelial cells w/ decreased microcomedo formation. Additionally, stimulates mitotic activity and increased turnover of follicular epithelial cells causing extrusion of the comedones.

PHARMACOKINETICS

Absorption: (Retin-A Micro Gel 0.1%) 0.82% (single applications), 1.41% (multiple daily applications for 28 days).

ASSESSMENT

Assess for drug hypersensitivity, sun exposure, sensitivity to sun, sunburn, eczematous skin, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for sensitivity reactions, irritation, local erythema or peeling at application site, and other adverse reactions. Closely monitor alterations of vehicle, drug concentration, or dose frequency by carefully observing therapeutic response and skin tolerance.

PATIENT COUNSELING

Instruct to d/c use and consult physician if irritation occurs. Instruct not to use more than the recommended amount and not to apply more than qd. Advise to minimize exposure to sunlight, including sunlamps, and to use sunscreen products and protective clothing over treated areas when exposure to sun cannot be avoided. Inform that weather extremes may be irritating to treated skin. Instruct to use ud, and to keep away from eyes, mouth, angles of the nose, and mucous membranes. Advise to inform physician of other acne preparations being used and if pregnant or breastfeeding. Inform that during the early weeks of therapy, an apparent exacerbation of inflammatory lesions may occur, which should not be considered a reason for discontinuation. **Retin-A Micro:** Advise to apply moisturizer if dryness is bothersome.

STORAGE

(Retin-A) Cre: <27°C (80°F). **Gel:** <30°C (86°F). **(Retin-A Micro) Gel:** 20-25°C (68-77°F); excursions permitted from 15-30°C (59-86°F). Store pump upright.

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