

DATA SHEET

RETIN-A

Tretinoin

Presentation

Cream: 0.05%: smooth, pale yellow, hydrophilic vehicle of polyoxyl 40 stearate, stearyl alcohol, stearic acid, isopropyl myristate, butylated hydroxytoluene, sorbic acid and xanthan gum.

Gel: 0.025%; in vehicle of butylated hydroxytoluene, hydroxypropyl cellulose, and alcohol 90% w/w. It is a smooth, clear, viscous yellow gel having an odour of alcohol.

Uses

Actions

Animal studies suggest that retinoic acid (tretinoin) is the tissue active metabolite of Vitamin A, and has been designated 'partial Vitamin A' in that it can stimulate the growth of Vitamin A deficient animals but it is unable to correct defective vision or impaired reproduction.

The therapeutic action of tretinoin on acne skin is unrelated to its physiological functions as a vitamin. The general effect is that the proliferative activity of epidermal cells is greatly enhanced, associated with changes in cellular differentiation (keratinisation and cornification), resulting in diminished keratinisation.

Absorption studies carried out on the intact skin of the forearm in the human have illustrated that only low sub-physiological dosing of Vitamin A occurs when tretinoin is applied to the skin. It is likely that absorption may be considerably increased when tretinoin is applied repeatedly to acne skin.

Indications

RETIN-A tretinoin Cream and Gel are indicated for topical application in the treatment of acne vulgaris, primary grades I-III in which comedones, papules and pustules predominate. They are not recommended as mono-therapy in cases of severe pustular and deep cystic nodular varieties (acne conglobata).

Dosage and Administration

RETIN-A Gel or Cream should be applied once a day, before retiring, to the skin where acne lesions appear, using enough to cover the entire affected area lightly.

During the early weeks of therapy, an apparent exacerbation of inflammatory lesions may occur. This is due to the action of the medication in deep, previously unseen lesions and should not be considered a reason to discontinue therapy.

Therapeutic results should be noticed after two to three weeks, but more than 6 weeks of therapy may be required before definite beneficial effects are seen. Once the acne lesions have responded satisfactorily, it may be possible to maintain the improvement with less frequent applications, or other dosage forms.

Contraindications

Use of the product should be discontinued if hypersensitivity to any of the ingredients is noted.

Warnings and Precautions

Warnings

Exposure to sunlight, including sunlamps, should be minimised during the use of RETIN-A, and patients with sunburn should be advised not to use the product until fully recovered because of heightened susceptibility to sunlight as a result of the use of tretinoin.

Patients who may be required to have considerable sun exposure due to occupation and those with inherent sensitivity to the sun should exercise particular caution. Use of sunscreen products and protective clothing over treated areas is recommended when exposure cannot be avoided.

Weather extremes such as wind or cold, also may be irritating to patients under treatment with tretinoin.

Medicated or abrasive soaps and cleansers, soaps and cosmetics that have a strong drying effect, and products with high concentration of alcohol, astringents, spices, or lime should be used with caution because of possible interaction with tretinoin.

RETIN-A should be kept out of the eyes, the mouth, angles of the nose and mucous membranes.

If medication is applied excessively, no more rapid or better results will be obtained and marked redness, peeling, or discomfort may occur.

Precautions

Use in Pregnancy and Lactation:

Reproduction studies performed in rats and rabbits at dermal doses up to 50 times the human dose (assuming the human dose to be 1000mg of cream or 500mg of gel per day) have revealed no evidence of impaired fertility or harm to the foetus due to tretinoin.

There was however, a slightly higher incidence of irregularly contoured or partially ossified skull bones in some rat and rabbit foetuses. There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should not be used by pregnant women or those planning to become pregnant during treatment.

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk caution should be exercised when RETIN-A is administered to a nursing mother.

Carcinogenicity

Photo carcinogenicity studies in hairless albino mice have given conflicting results. Some studies show acceleration, some inhibition and others no effect on the tumorigenic potential of ultra-violet radiation. Topical administration of tretinoin in the absence of ultraviolet radiation showed no indication of tumorigenicity. Although the significance to man is not clear, patients should avoid or minimise exposure to sun.

Adverse Effects

RETIN-A (tretinoin) acne treatment should be kept away from the eyes, the mouth, angles of the nose, and mucous membranes. Topical use may induce severe local erythema and peeling at the site of application.

If the degree of local irritation warrants, patients should be directed to use the medication less frequently, discontinue use temporarily, or discontinue use altogether.

Tretinoin has been reported to cause severe irritation on eczematous skin and should be used with utmost caution in patients with this condition.

The skin of certain sensitive individuals may become excessively red, oedematous, blistered, or crusted.

If these effects occur, the medication should be discontinued until the integrity of the skin is restored, or the medication should be adjusted to a level the patient can tolerate.

True contact allergy to topical tretinoin is rarely encountered. Temporary hyper- or hypopigmentation has been reported with repeated application of RETIN-A. Some individuals have been reported to have heightened susceptibility to sunlight while under treatment with RETIN-A.

To date, all adverse effects of RETIN-A have been reversible upon discontinuance of therapy.

Interactions

Concomitant topical medication should be used with caution because of possible interaction with tretinoin. Particular caution should be exercised in using preparations containing peeling agents (such as sulphur, resorcinol, or salicylic acid) with RETIN-A. It also is advisable to "rest" a patient's skin until the effects of peeling agents subside before use of RETIN-A is started.

Overdosage

RETIN-A is indicated for topical use only. If used excessively, no more rapid or better results will be obtained and marked redness, peeling or discomfort may occur. Oral ingestion of the drug may lead to the same side effects as those associated with excessive oral intake of vitamin A.

Medicine Classification

Prescription medicine.

Package Quantities

Cream 0.05% 20g
Gel 0.025% 60g

Pharmaceutical Precautions

All RETIN-A topical preparations should be stored below 25°C.

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