A-RET®

(tretinoin)

MEDPHARMA

PHARMACEUTICAL PRESENTATIONS:

A-RET CREAM

COMPOSITION:

Cream: 30gm contains tretinoin (retinoic acid) 0.05% w/w

PHARMACODYNAMIC PROPERTIES:

Although the exact mode of action of tretinoin is unknown, current evidence suggests the effectiveness of the tretinoin in acne is primarily due to its ability to modify abnormal follicular keratinization. Acne comedones form in follicles with excessively keratinized epithelial cells. The accumulation of keratinized material in the follicle initiates comedone formation. Tretinoin promotes detachment of cornified cells and enhanced shedding of corneocytes from the follicle. By increasing the mitotic activity of follicular epithelia, tretinoin also increases the turnover rate of thin, loosely-adherent corneocytes. Through these actions, tretinoin prevents formation of microcomedo, the precursor lesion of acne vulgaris. Additionally, tretinoin acts by modulating the proliferation and differentiation of skin cells. These effects are mediated by tretinoin's interaction with a family of nuclear proteins,retinoic acid receptors. Activation of these nuclear receptors causes changes in gene expression, which in turn, modify abnormal cellular processes. The exact mechanisms whereby tretinoin-induced changes in gene expression regulate skin function are not understood.

INDICATION:

A-RET is indicated as topical therapy for the treatment of acne vulgaris.

RECOMMENDED DOSAGE:

Adults:

A-RET should be applied once daily before retiring to the area of skin where acne lesions occur. Only a sufficient quantity of medication should be applied to cover the affected areas lightly, using a gauze swab, cotton wool or the tips of clean fingers. Over-saturation should be avoided since excess medication could run into the eyes, angles of the nose or other areas where treatment is not intended.

Application of **A-RET** may cause a transitory feeling of warmth or slight stinging. When administered according to recommended guidelines, **A-RET** may produce a slight erythema similar to that of mild sunburn. In cases where it is necessary to temporarily discontinue therapy or reduce the frequency of application, therapy should be resumed or frequency application increased when patient becomes able to tolerate the treatment.

Excess application of **A-RET** does not provide more rapid or better results. In fact, marked redness, peeling or discomfort can occur. If excess application occurs accidentally or through over-enthusiastic use, **A-RET** should be discontinued for several days before resuming therapy.

Therapeutics effects may be noticed after two to three weeks of use but more than six weeks of therapy may required before definite beneficial effects are seen. During the early weeks of treatment, an apparent exacerbation of inflammatory lesions may occur. This is due to the action of the medication on deep, previously unseen lesions and should not be considered a reason to discontinue therapy. Once a satisfactory response has been obtained, it may be possible to maintain this improvement with less frequent applications.

Prior to treatment with **A-RET**, areas being treated should be thoroughly cleansed with water and a mild, non-medicated soap. The treated area should be washed no more than twice a day. After washing, the skin should be dried gently and completely without rubbing it. Areas of the skin being treated should be allowed to dry for at least 20 to 30 minutes before application of **A-RET**.

Cosmetics and moisturizers may be used during therapy with **A-RET**, but the areas of the skin to be treated should be washed thoroughly before **A-RET** is applied. Astringent toiletries should be avoided.

CONTRAINDICATIONS:

A-RET is contraindicated in patients with ;

- A history of sensitivity/hypersensitivity reactions to any of the components of this product.
- Personal or familial history of cutaneous epithelioma.
- Acute eczemas.
- Rosacea and perioral dermatitis.

WARNINGS:

GENERAL PRECAUTIONS

- In order to minimize the potential for additional skin irritation, care should be taken to avoid contact with eyes, eyelids, angles of the nose, mouth, mucous membranes or other areas where the treatment is not intended.
- Patients will be able to remove hair as usual (e.g. plucking, electrolysis, depilatories but should avoid these procedures at night before applying **A-RET** as they might result skin irritation.
- Permanent wave solutions, waxing preparations, medicated soaps and shampoos can sometimes irritate even normal skin. Caution should be used so that these products do not come into contact with skin treated with **A-RET**.

LOCAL IRRITATION

- It is not recommended to initiate treatment with **A-RET** or continue its use in the presence of skin irritation (e.g. erythema, peeling, pruritus, sunburn, etc.) until these symptoms subside.
- Weather extremes, such as wind, cold and low humidity may be irritating to skin treated with **A-RET** and may increase its dryness.

EXPOSURE TO SUNLIGHT

- Exposure to sunlight, including ultraviolet sunlamps, may provoke additional irritation. Therefore, exposure should be avoided or minimized during the use of tretinoin.When exposure to sunlight cannot be avoided, use of sunscreen products and protective clothing over treated areas is recommended.

CHILDREN

- Safety and effectiveness have not been established in children.

PREGNANCY AND LACTATION

- There have been no adequate and well-controlled prospective studies performed in pregnant women and the teratogenic blood level of tretinoin is not known.
- Topical tretinoin should be used during pregnancy only if potential benefit justifies the potential risk to the fetus.
- Since many drugs are excreted in human milk, caution should be exercised when **A-RET** is administered to a nursing mother.

UNDESIRABLE EFFECTS:

Some degree of local irritation is expected. The most commonly reported undesirable effects are dry skin, burning, stinging, warmth, erythema, pruritus, rash, peeling and temporary hypo-and hyperpigmentation. Rarely reported undesirable effects are blistering and crusting of the skin,eye irritation and edema.

INTERACTIONS:

Concomitant topical medication, medicated or abrasive soaps and cleaners, soaps and cosmetics that have a strong drying effect, and products with high concentrations of alcohol, astringents, spices or lime should be used with caution because of possible interaction with tretinoin. Particular caution should be exercised in using preparations containing sulfur, resorcinol, or salicylic acid with **A-RET**. It is also advisable to "rest" a patient's skin until the effects of such preparations subside before use of **A-RET** is begun.

OVERDOSAGE:

Topical application of **A-RET** is characterized by little systemic absorption, hence overdosage is unlikely.

Excessive application of **A-RET** does not improve the results of treatment and may induce marked irritation, e.g., erythema, peeling, pruritus, etc. Oral ingestion of **A-RET** may lead to the same effects associated with excessive oral intake of Vitamin A)e.g. pruritus, dry skin, arthralgias, anorexia, vomiting). In the event of accidental ingestion, if the ingestion in recent, an appropriate gastric emptying should be used as soon as possible.

STORAGE:

- Store below 25°C. Protect from direct light.
- Do not refrigerate.
- Do not use after the expiry date stated on the pack.
- Do not use if there is any physical change on the product.
- Keep out of reach of children.

PACKAGING PRESENTATION:

A-RET CREAM: Collapsible Aluminum tube of 30gm.

THIS IS A MEDICAMENT

Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

Mfd. by:

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