RETACNYL cream

Tretinoin

FORMS AND PRESENTATION

Dermal cream containing 0.05% tretinoin. Tube containing 30 g.

COMPOSITION

	per 100 g	*per tube*
Retacnyl 0.05%		
Tretinoin (INN)	50 mg	15 mg

Excipient: polyethylene glycol stearate, Arlacel 165, cetyl alcohol, stearyl alcohol, squalane, stearic acid, Carbopol 941R, glycerin, Disodium edetate, triethanolamine, isopropyl myristate, purified water. *Preservatives:* butylated hydroxyanisole, butylated hydroxytoluene, propyl parahydroxybenzoate, methyl hydroxybenzoate.

PROPERTIES

Tretinoin applied to the skin is responsible for a variety of effects on cellular systems. It stimulates mitosis and epidermal cell renewal, inhibits the formation of keratin, activates conjunctive tissue repair and can avert and even achieve regression of skin tumours induced by a variety of carcinogens. These properties form the basis for the use of tretinoin in dermatology in the treatment of skin infections such as acne, psoriasis, ichthysis and actinic keratosis.
In acne, tretinoin acts on one of the essential aetiological factors, which is the keratinization of the lower part of the pilosebaceous follicle. The keratinized cells adhere strongly to each other, obstructing the pilosebaceous orifice which dilates, forming the microcomedo. The sebaceous gland, plugged by the effect of sebum production, becomes encysted, forming a microcyst or closed comedo. This closed comedo may evolve into an open comedo or blackhead. The microcysts are the site of a microbial pullulation of Staphylococcus albus and Propionibacterium acnes. These organisms liberate lipases which prematurely transform triglycerides into free fatty acids which emerge in the dermis through the follicle wall, triggering an inflammatory reaction with a degree of suppuration, corresponding to the formation of papules and pustules. In the course of this suppurative phase, deep cystic nodules can be formed. Their evolution is prolonged, interspersed with inflammatory phenomena. The activity of tretinoin is based on a mechanism of action which has an application at every stage in the pathogenesis of acne.

- tretinoin opposes and averts the formation of those elements which cause acne : by stimulation of the follicular epithelium, the increased proliferation of non-coherent keratinized cells is intensified. These unattached corneal cells are evacuated together with sebum towards the surface of the skin. The corneal plug cannot evolve and the formation of new elements is thus forestalled;
- tretinoin provokes the expulsion of retentive elements (open comedones, microcysts). Beyond the superficial desquamation of the epidermis, tretinoin exerts a deep action at the level of the follicular epithelium: it stimulates the proliferation of free corneal cells which, in association with the reduction in coherence of the corneal plug, leads to the expulsion of microcysts or of the comedo;
- tretinoin accelerates the evolution of inflammatory elements (papules, pustules). Applied at the onset of the inflammatory phase, tretinoin increases the permeability of the follicular wall to irritants responsible for inflammatory phenomena (fragments of keratin, free fatty acids etc.) and equally accelerates the evolution of papules and pustules and their elimination. It thus prevents the transformation of these lesions into cystic nodules.

FATE OF THE MEDICAMENT

Systemic absorption of tretinoin after cutaneous application of RETACNYL cream is practically nil.

INDICATIONS

All forms of acne with the exception of acne rosacea.
Keratinisation disorders; in particular forms of parakeratosis, hyperkeratosis and dyskeratosis, primarily of genetic, hereditary, family origin, inaccessible to conventional treatment.

PRECAUTIONS

- In view of possible intolerance phenomena such as oedema or an eczema episode of a transitory nature, repeated testing on a small skin area (touch test) is desirable when the treatment is first applied.
- Abstain from washing too frequently; twice a day is sufficient. The use of gentle soap and shampoo is recommended.
- Avoid the use of perfumes, eau de cologne, skin tonic and before- or after-shave lotion and, generally, any product containing perfume or alcohol which might cause marked irritation.
- Avoid contact with the eyes, eyelids, mouth, nostrils, mucous membranes. If affected, wash the area carefully with water. However, on hyperkeratotic lesions of the oral or genital mucosa (such as leukoplakia, leukokeratosis, erosive lichen, the product has an irritant effect due to the nature of the hyperkeratosis itself).
- Particular prudence is required in simultaneous treatment with other local preparations, especially those with a desquamative effect. If, prior to RETACNYL treatment, the patient has already been treated with keratolytic or exfoliative preparations, it is recommended to await the end of any cutaneous irritant phenomena.
- Exposure to sunlight and ultraviolet lamps provokes supplementary irritation. Avoid exposure, as far as possible, during treatment with RETACNYL.
- Treatment can, however, be maintained if solar exposure is kept to a minimum (a hat should be worn and a sunscreen cream used) and by adjustment of the timing of application.
  In the event of exceptional exposure to sunlight (a day by the sea, for example), RETACNYL should not be applied the day before, on the day or the day after.
  If prior exposure has led to sunburn, await complete recovery before undergoing RETACNYL treatment.

Pregnancy:

- Animal studies have shown tretinoin to be teratogenic via the oral route. Via the topical route and at high dosages, it induced minor skeletal malformation.
- In man, these limited data suggest logically that preparations containing tretinoin should not be used during the first 3 months of pregnancy. Nevertheless, in the human species, percutaneous absorption is poor and no risk of malformation has been demonstrated.

DRUG INTERACTIONS

By reason of the irritative nature of the molecule, it is preferable to avoid any preparation likely to induce local irritation (alcohol-based lotions in particular).

SIDE EFFECTS:

Local side effects can occasionally arise in the form of irritative phenomena characterised by a dry, slightly overheated erythema, sited mainly in the perioral and neck regions. These phenomena, directly allied to the activity of the product, disappear if frequency of application is reduced, however. During the first few weeks of treatment, it is possible that a re-eruption of acne may occur, notably in the form of small, white-headed pustules. This reaction is normal: it consists of the accelerated elimination of microcysts which were in the process of forming at a lower skin level.

DOSAGE AND ADMINISTRATION:

Spread small amount of cream on the lesions to be treated and lightly massage with the fingertips. Generally, one application daily, in the evening, after washing and allowing the lesions to dry for 15 min before treating the lesions. Wash hands after use of the preparation.

- Acne, treatment regime;

Initial treatment consists of one application, in the evening, then frequency of application is adjusted on the basis of the reactions obtained.
In the event of severe primary irritation, move to one application every other day.
In the absence of any local reaction, frequency of application may be increased to twice a day.
From the end of the second week up until the end of acute treatment (week 12 to 14), the frequency of application is on average once a day or less in the event of persistent irritation.
The frequency of application and concentration prescribed must be such as to avoid disagreeable irritation; only slight erythema, moderate desquamation and possibly a slight burning sensation are acceptable. Stronger reactions on the part of subjects with delicate skin, blond or red hair, must be anticipated and an appropriate dosage regimen chosen. The primary irritation is supplemented, towards week 2, by an increase in papules and pustules corresponding to the inflammatory evolution of microcysts which is accelerated by the treatment and occurs in a specific interval after its onset; this efflorescence is not recurrent and a gradual improvement takes place thereafter. This reaction is normal and confirms the activity of the treatment; frequency of application should not be adjusted on its account. It is at this time that the doctor-patient relationship is of the greatest importance. An informed patient, motivated, very regularly monitored and given moral support during the temporary phase of primary irritation and efflorescence, accepts the treatment with optimism and all the more so, the more severe, long-lasting, profuse and desperate the acne condition is.
Improvement is clearly visible towards the sixth week of treatment and continues until the optimal result is achieved in about the twelfth or fourteenth week. At that time, or earlier if all acne signs have disappeared, a move to maintenance treatment of 2 or 3 applications per week is possible.
To obtain the optimal result, the patient must be alerted to the normal reactions which may be expected after onset of treatment: primary irritation and transitory erythema. Regular monitoring is required so that dosage may be adjusted and primary irritation reduced to a minimum. The patient should be warned of the delay in onset of improvement, the value of complying with the full 3-month programme of therapy if the optimal result is to be achieved and the need for maintenance treatment to avoid recurrence.

- In keratinisation disorders:

The frequency of application and the mode (occlusive dressing, massage, dabbing...) are at the discretion of the prescriber and will depend on the extent of the lesions and their severity and the particular nature of the infection. The recommended frequency of treatment of 1 to 2 applications per day will be adjusted according to the patient's reactions. In cases of major primary irritation, it may be reduced to one application every other day, or one every three days.
Note: in the case of hyperkeratosis of the oral mucosa, the product may be applied directly to the lesions with the aid of cotton buds.

OVERDOSAGE

Excessive use will only lead to a disagreeable skin reaction but will not improve the results of treatment.