



Technical Data sheet

TRETINOINA Ph.Eur. (Acido trans-Retinoico)		
DESCRIPTION DCI: TRETINOIN		DESCRIPTION DOE: TRETINOINA
CAS Nº: 302-79-4	EC Nº: 206-129-0	AEMPS CODE: 155A
MOL. WEIGHT: 300,44	MOL. FORMULA: C ₂₀ H ₂₈ O ₂	ARTICLE CODE: 000223

ATTRIBUTES	SHOULD BE
Appearance	Yellow or light-orange, crystalline powder
Solubility	Practically insoluble in water, sparingly soluble in methylene chloride, slightly soluble in ethanol (96 %)
Melting point	about 182 °C, with decomposition
Identification A	Complies
Related substances	
Impurity A	= < 0.5 %
Any other impurity	= < 0.2 %
Total impurities	= < 1.0 %
Loss on drying	= < 0.5 %
Sulfated ash	= < 0.1 %
Assay	98.0 - 102.0 %
Residual solvents	
Acetaldehyde	= < 15 ppm
Ethyl acetate	= < 5000 ppm
Microbiological control	
TAMC	= < 100 CFU/g
TYMC	= < 100 CFU/g
Salmonella	Absent/g
S. Aureus	Absent/g

COMPLIES WITH

European Pharmacopoeia 9.0

STORAGE

Store the containers in a dry and well-ventilated place, away from sources of heat and direct sunlight.

REMARKS

Tretinoin is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE are available upon request.

Properties and uses

Trans-retinoic acid (or tretinoin) seems to stimulate mitosis and metabolism of follicular epithelial cells, reducing cohesion and facilitating the extrusion of existing comedones and preventing the formation of new ones by keratolytic effect. It also seems that the thickness of the stratum corneum decreases. It is used mainly in the topical treatment of acne vulgaris, especially in which comedones, papules, and pustules predominate, in the form of creams, gels, and hydroalcoholic solutions. The therapeutic response against acne is not evident until after 6 or 8 weeks of treatment, and even in the first phases of treatment hidden comedones may appear. Once acne has resolved, applications should be less frequent. It is also used in cases of ichthyosis, psoriasis, lichen planus, palmoplantar keratoderma, warts, papillomas, and actinic keratosis. Finally, it has a preventive effect on the appearance of wrinkles.

Dosage

Topical route, 0.01 - 0.1%, normally 1-2 times a day (although this may vary depending on the patient, the response, irritation ...). In keratosis plantar and disorders of keratinization genetic or resistant to other treatments has been used up to 0.3%. As an anti-wrinkle agent, usually at 0.025 - 0.01% (sometimes more). For oral lichen planus, 0.1% in oral



Technical Data sheet

TRETINOINA Ph.Eur. (Acido trans-Retinoico)		
DESCRIPTION DCI: TRETINOIN		DESCRIPTION DOE: TRETINOINA
CAS Nº: 302-79-4	EC Nº: 206-129-0	AEMPS CODE: 155A
MOL. WEIGHT: 300,44	MOL. FORMULA: C ₂₀ H ₂₈ O ₂	ARTICLE CODE: 000223

adhesive excipient.

Side effects

Retinoic acid is an irritant to the skin. During the first minutes of its application it can produce burning sensation and burning sensation. With the use it produces erythema and "peeling" (similar to that which occurs with minor sunburn). Depending on the individual sensitivity, the effects vary, from edemas to blisters or scabs. Other side effects are photosensitivity, and hyper and hypopigmentation. They are usually reversible symptoms, which subside when treatment is interrupted, but changes in pigmentation may persist for months.

Contraindications

Hypersensitivity to tretinoin. Pregnant patients and nursing mothers.

Precautions

Retinoic acid should not be applied to the eyes, mouth and nose, and other mucous surfaces, nor on damaged, eczematous skin, with open wounds, with abrasions, or burned by the sun. Do not use in conjunction with other topical therapies, especially with keratolytic agents, as well as excessive use of soap, but it can be used with benzoyl peroxide, with an interval of 12 to 24 hours between each application. You must avoid or minimize sun exposure or solar lamps, or protect yourself with creams and appropriate clothing.

Incompatibilities

Strong oxidizing agents.

Other observations

The product is served packed under a nitrogen atmosphere. All operations with the product must be carried out as quickly as possible, since it is very sensitive to air, heat and light. It is advisable not to give more than 1 month of expiration to the formulations. Add an antioxidant to the formulations (eg BHT 0.03%, or BHT 0.05% / BHA 0.05%).