

94349-RETINOIC ACID**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1 Identification of the substance or preparation.**

Name: Retinoic acid

Bulk code: 94349

1.2 Synonyms.

Tretinoinum; trans-retinoic acid; vitamin A acid; tretinoin.

2. DESCRIPTION

Appearance: Crystalline powder

Colour: Yellowish to pale orange

3. COMPOSITION/INFORMATION ON COMPONENTS.Formula: $C_{20}H_{28}O_2$

MW: 300.4 g/mol

CAS: 302-79-4

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis bulletin.

Solubility: Practically insoluble in water, sparingly soluble in ethanol (96%) and chloroform. Fairly soluble in ether and soluble in methylene chloride.**Melting point:** Approximately 182 °C with decomposition.**5. PROPERTIES/USES.**

ACTIVE PHARMACEUTICAL INGREDIENT.

Retinoic acid is used in the treatment of acne vulgaris with comedones, papules and pustules. It stimulates mitosis and metabolism of the follicular epithelium cells, reducing cohesion, facilitating the extrusion of existing comedones and preventing the formation of new ones. It also appears to decrease the thickness of the stratum corneum.

Given its keratolytic action, it is used in cases of ichthyosis, psoriasis, lichen planus, hyperkeratosis, palmoplantar keratoderma, warts, papillomas and actinic keratosis. It is often combined with other keratolytics, corticosteroids and reducing keratoplastics.

It is prescribed as an anti-wrinkle treatment in order to prevent their appearance.

94349-RETINOIC ACID

6. DOSAGE.

Acne:

- Topical use: in the form of creams, gels and hydroalcoholic solutions, at a concentration of 0.01-0.1%, with the skin having been cleaned to remove excess oil and dried 15-30 minutes before use.
- Oral use, in doses of 5-16 mg, once daily, on an empty stomach.

Cutaneous lichen planus:

- Oral use, in 16 mg capsules, once daily, on an empty stomach, as for topical use.

Oral lichen planus:

- Oral use in doses of 10 mg, three times a day, one hour before meals, or orally, at 0.1% in an oral adhesive excipient.

Anti-wrinkle:

- Initially at 0.01%, subsequently increased to 0.025%, and then to 0.05% and higher.

Acute promyelocytic leukaemia:

- Daily 45 mg/m² body surface area, divided into two doses.

7. REMARKS.

STORAGE:

Store at room temperature (25±2°C) in hermetically sealed containers, in a dry, well ventilated place away from light.

It is highly unstable in the presence of oxygen or light. Handle within an inert gas atmosphere.

8. BIBLIOGRAPHY.

Monografías Farmacéuticas, C.O.F. de Alicante (1998).

"Martindale. The extra pharmacopoeia. 30 (1993).