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TECHNICAL DATA SHEET

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5.0

94346-13-CIS-RETINOIC ACID

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1 Identification of the substance or preparation.

Name: 13-cis-retinoic acid

Bulk code: 94346

1.2 Synonyms.

Isotretinoinum; Cis-retinoic acid; Isotretinoin; 13-Z-retinoic acid; 13-cis-vitamin A acid; Isotretinoin.

2. DESCRIPTION

Appearance: Crystalline powder.

Colour: Yellow or pale orange.

Smell: Practically odourless.

3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula: $C_{20}H_{28}O_2$

CAS: 4759-48-2

Molecular weight: 300.4 g/mol

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis report.

Solubility: Practically insoluble in water; highly soluble in ether. Soluble in chloroform and methylene chloride; poorly soluble in ethanol, isopropanol and polyethylene glycol.

Melting point: 175°C

5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

Isotretinoin is highly effective against severe nodulocystic acne that is resistant to other treatments. Clinical remissions usually appear within a month of starting therapy and are often maintained for months or years after the medication is stopped, the duration of which is usually 16 weeks. Some physicians advise extending the indications of 13-cis-retinoic acid to inflammatory papulopustular acne with scars, to folliculitis caused by gram-negative



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germs, to severe acne rosacea and to certain resistant cases of hidradenitis suppurativa. It should not be given in uncomplicated adolescent acne.

It appears to act like its stereoisomer, tretinoin, which has a keratolytic effect by preventing the layers of corneal cells from joining together, altering the formation of comedones.

Isotretinoin is also used in cases of psoriasis and other skin conditions.

6. DOSAGE.

Orally:

Initial dose for cases of acne: 500 micrograms at 1 mg/kg of weight per day, in one or two doses with meals; after 2–4 weeks, the dosage should be adjusted according to the individual's response. In patients with initial dose intolerance, treatment may be continued with 100–200 micrograms/kg of weight daily.

Topically:

In the form of a cream or gel at a concentration of 0.05 %, once or twice a day.

7. REMARKS.

STORAGE:

Store at room temperature ($25\pm 2^{\circ}\text{C}$), in a cool, dry place, away from sunlight, in a tightly closed container.

It is very sensitive to air, heat and light, especially in solution. It is recommended all operations be carried out as quickly as possible, avoiding exposure to actinic light and using solutions immediately after their preparation.

8. BIBLIOGRAPHY.

Monografías Farmacéuticas. COF Alicante, 1998.

"Martindale. The Extra Pharmacopoeia". 30th Edition. Ed. The Pharmaceutical Press. London. (1993).