



GUINAMA. Laboratory distributing raw materials for the pharmaceutical and cosmetics industries.

Type of Document:

**TECHNICAL DATA SHEET**

Fecha revisión:

08.09.2022

Versión:

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## 94064-17-BETA ESTRADIOL

### 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

#### 1.1 Identification of the substance or preparation

Name: 17-Beta estradiol

Bulk code: 94064

#### 1.2 Synonyms

Estradiolum; Dihydrofolate; Dihydrotheelin; Dihydroxyestratrien; Dihydroxyestrin;  
Estradiol;  $\beta$ -estradiol; cis-estradiol; 3,17-epidihydroxyestratrien; Femestral;  
Dihydrofollicular hormone; Profoliol.

### 2. DESCRIPTION

Appearance: Crystalline powder or crystals.

Colour: White or almost white (powder) or colourless (crystals) Smell: Odourless

Method of production: Obtained from plant-based phytosterols (soya) and subsequent chemical handling so they are identical to phytosterols of human origin. (Bioidentical).

Particle size: Not micronized but smaller than 20 microns

### 3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula:  $C_{18}H_{24}O_2, \frac{1}{2} H_2O$

CAS: 35380-71-3

Molecular weight: 281.4 g/mol

### 4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis report.

**Solubility:** Practically insoluble in water; soluble in 28 p. alcohol, 435 p. chloroform and 150 p. ether. Soluble in acetone, dioxane and aqueous alkali hydroxide solutions. Slightly soluble in vegetable oils and dichloromethane.

**Melting point:** 175–180°C

### 5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

1.03 g of estradiol hemihydrate is equivalent to 1 g of estradiol anhydrous; approximately 1 mg of estradiol contains 10000 I.U.



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Estrogens are the hormones responsible for the growth and development of the female sex characteristics: maturity of the vagina and uterus, and development of the breasts, maintaining the organic structure and functional capacity of the female genitalia.

It is used in hormone replacement therapy to prevent the symptoms and metabolic changes associated with the loss of ovarian function caused by the menopause. Estradiol and its semi-synthetic esters are used in cases of estrogen deficiency, such as atrophic vaginitis, menopausal atrophic dystrophy of the vulva, vasomotor symptoms of the menopause and osteoporosis prevention. It is also used to treat signs of deficiencies after an ovariectomy or actinic castration caused by non-neoplastic diseases.

Prolonged treatment with estrogens increases the rate of endometrial hyperplasia and carcinoma; to alleviate this risk, additional administration of progesterone is recommended during the final 12 days of the menstrual cycle.

It is also used, like other estrogens, in prostate cancer metastasis and breast cancer in men and postmenopausal women, generally at high doses.

### **6. DOSAGE.**

Orally: Doses of 1-2 mg/day, after each meal, for 20 days, with 1 week's rest and continuing for several cycles.

Vaginally in cream format: 0.01% daily, up to a maximum of 4 g/day.

Vaginal tablets: 25 mcg, starting with 1 tablet per day for 2 weeks and continuing with 2 tablets each week.

Topical gel: 1.5 mg of estradiol in 2.5 g of gel, absorbing approximately 10%. It should not be administered on the chest or surrounding areas, nor in the vulvar region.

Transdermal patches: at concentrations of up to 100 mcg per day, replaced every 3-4 days. These patches must be applied to different areas, avoiding the chest and nearby areas.

Transdermal creams (that ratify a systemic dose per application): up to 100 mcg.

Subcutaneous implants of beta-estradiol: doses of 25-100 mcg, with a new implant every 4-8 months.

Topically in hydroalcoholic solutions: of 0.025% to treat alopecia in women with polycystic ovary syndrome.



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## 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.

## 8. BIBLIOGRAPHY.

Pharmaceutical Monographs. COF Alicante, 1998.

"Martindale. The Extra Pharmacopoeia". 37th Edition. Ed. The Pharmaceutical Press. London. (2011).