



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

Type of Document:

TECHNICAL DATA SHEET

Fecha revisión:

13.09.2022

Versión:

6.0

93685-MICRONIZED PROGESTERONE

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1 Identification of the substance or preparation

Name: Micronized progesterone

Bulk code: 93685

1.2 Synonyms

Progesteronum; Dioxopregnene; Corpus luteum hormone; Luteum hormone; Lutein; Pregnenedione; Progestin.

2. DESCRIPTION

Appearance: Crystalline powder or crystals.

Colour: White or almost white (powder) or colourless

(crystals) Scent: Odourless

Flavour: Insipid.

Origin: Plant. Made from natural diosgenins found in yam. Stable in air.

3. COMPOSITION/INFORMATION ON COMPONENTS.

Formula: $C_{21}H_{30}O_2$

CAS: 57-83-0

Molecular weight: 314.5 g/mol

4. PHYSICO-CHEMICAL DATA.

See detailed specifications in analysis report.

Solubility: Practically insoluble in water. Soluble in 8 p. alcohol, 60 p. peanut oil, 16 p. ether, 60 p. ethyl oleate, 100 p. petroleum ether and less than 1 p. chloroform. Slightly soluble in acetone, dioxane and fixed oils.

Melting point: 128 - 132°C.

5. PROPERTIES/USES.

ACTIVE PHARMACEUTICAL INGREDIENT.

This is a natural progestogen secreted by the corpus luteum. It is necessary for egg implantation and to maintain a pregnancy as its release during the luteal phase of the cycle leads to the development of a secretory endometrium.

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Progesterone has multiple applications in treatments. It is used to treat dysfunctional uterine bleeding, dysmenorrhea, premenstrual tension, impending routine miscarriage, benign breast diseases, perimenopause, menopause, infertility due to a luteal phase defect, and for contraception, in vitro fertilisation techniques, gamete intrafallopian transfer techniques, etc.

Orally, it is prescribed to treat luteal phase defects such as premenstrual syndrome, benign breast diseases, menstrual irregularities and perimenopause, infertility due to a luteal phase defect, a risk of miscarriage or to prevent recurrent miscarriages due to a proven luteal phase defect, as well as in vitro fertilisation techniques of gamete intrafallopian transfer techniques.

Vaginally, it is used for the same cases as the oral method.

Topically, it is used to treat benign breast diseases, such as mastalgia, mastopathy and to prevent relapses in the case of cysts or adenofibromas.

As it has a local anti-androgen effect, it somewhat paralyses the alopecia stimuli while regulating sebaceous secretion, which is why it is recommended in processes involving hyperseborrhea, like facial and scalp seborrheic dermatitis, polymorphic juvenile acne, pityriasis amiantacea and seborrheic alopecia.

Hormone Replacement Therapy: As we age, we suffer a reduction in hormone production; hormone replacement therapy replaces those hormones that the body needs to work correctly. It uses bioidentical hormones that are chemically identical to those produced by the human body.

6. DOSAGE.

Orally, the usual dose is 200-300 mg/day, divided into two intakes, one in the morning and the other at night before bed. It is not very effective via this form of administration as its efficacy is irregular and limited.

Vaginally, it is used in transparent capsules with identical doses.

Topically, it is used in a range of concentrations from 1-10% in the form of a gel, ointment or cream.

In cases of local anti-androgen action, its concentrations range from 0.5 to 5% alone or associated with other active ingredients.

In hormone replacement therapy, the doctor will assess the individual's need to re-establish these hormones and create a specific medical plan for the patient.



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7. REMARKS.

STORAGE:

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

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

8. BIBLIOGRAPHY.

Pharmaceutical Monographs. COF Alicante, 1998.

"Martindale. The Extra Pharmacopoeia". 37th Edition. Ed. The Pharmaceutical Press. London. (2011). Bodylogicmd. Bioidentical Hormone Therapy. MonoNote. Bioidentical Hormones.