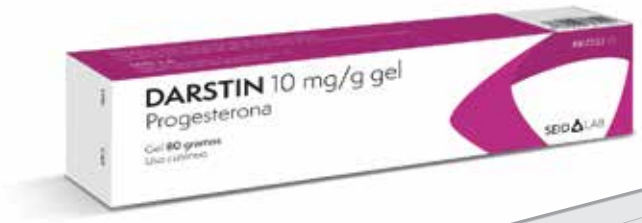
DARSTIN®

topical natural progesterone



POSOLOGY:

1 measure of applicator per day (2.5g) on each breast

1. NAME OF THE MEDICINAL PRODUCT: darstin 10 mg/g gel. **2.QUALITATIVE AND QUANTITATIVE COMPOSITION.** Each gram of gel contains: 10 mg of progesterone. For a list of excipients, see section 1 .6. **3. PHARMACEUTICAL FORM.** Translucent gel. **4. CLINICAL DATA. 4.1. Therapeutic indications.** Specific treatment of benign breast disease, Mastodinias, Painful breast tenderness isolated or associated with: Contraceptive treatments, premenstrual syndromes, start of pregnancy, benign mastopathies. . **4.2. Posology and method of administration:** Posology: Apply 5 g of gel on the skin of the breasts (a measurement of the spatula in each breast) every day, even during menstruation. The duration of treatment depends on the indication and is determined by the doctor according to the individual. Method of administration: Cutaneous use. Take the spatula by its end, the tube with the other hand and extend the gel along the spatula. This amount is the correct dose for one breast (2.5 g). Repeat the operation for the other breast. **4.3. Contraindications.** Hypersensitivity to the active substance or to any of the excipients included in section 6.1. **4.4. Special warnings and precautions for use.** As it is a hydroalcoholic solution, it should not be applied directly to mucous membranes. Frequent applications can cause skin irritation and dryness. **4.5. Interaction with other medications and other forms of interaction.** In the studies carried out, no significant clinical interaction was observed. **4.6. Fertility, pregnancy and lactation.** The data obtained does not indicate that Darstin has influence during pregnancy. Since Darstin lacks systemic effects, it can be used during lactation. **4.7. Effects on ability to drive and use machines.** Darstin has no influence on the ability to drive and use machines. **4.8. Adverse reactions.** Usually Darstin does not produce adverse effects. However, those described below could be presented: Disorders of the skin and subcutaneous tissue. Frequency not known (can not be estimated from the available data): irritation and dryness of the skin. Notification of suspected adverse reactions. It is important to report suspected adverse reactions to the medication after authorization. This allows a continuous monitoring of the benefit / risk ratio of the medicine.Health professionals are invited to report suspected adverse reactions through the Spanish Pharmacovigilance System for Medicinal Products for Human Use: www.notificaRAM.es. **4.9. Overdose.** Due to the particular pharmacokinetics of the product, the risk of overdosing is a null. **5. PHARMACOLOGICAL PROPERTIES. 5.1. Pharmacodynamic properties.** Pharmacotherapeutic group: progestagens derived from 4 pregnant women. ATC code: G03DA04. Mechanism of action. Darstin is a pure progesterone dispersed in a suitable excipient to be administered percutaneously. Due to its antiestrogenic action, it corrects locally the imbalance between estrogen and progesterone. It acts directly at the level of the mammary gland, in which the hormone is concentrated. In general Darstin does not produce adverse effects, so it has a good tolerance. Darstin prevents the vascular and cellular effects of local deficiency in progesterone locally in the mammary glands. At this level, progesterone: Prevents an increase in capillary permeability caused by estrogen. It acts on the growth and differentiation of galactophores and acini. It blocks the cycle of epithelial mitosis caused by estrogen. **5.2. Pharmacokinetic properties** Absorption. The absorption coefficient is around 10% of the dose administered. Biotransformation. 80% of the absorbed drug is metabolized in the mammary gland, while only 20% reaches the systemic circulation. Elimination. The maximum elimination of the metabolites takes place after 48 hours. **5.3. Preclinical safety data.** Safety tests and local tolerance: In the studies carried out, the skin surface where the product was applied has been observed regularly and also at the end of the treatment. The cutaneous surface of application remains intact after the end of the treatment. **6. PHARMACEUTICAL DATA. 6.1. List of excipients.** Carbomers Trolamine 96% Ethanol Purified water. **6.2. Incompatibilidades.** They have not been described. **6.3. Period of validity.** 3 years. **6.4. Special precautions for storage.** Store below 25°C and keep the container perfectly closed after each application. **6.5. Nature and contents of the pack.** Lacquered aluminum tube with internal gold varnish and blind mouth, 80 g, with dosing spatula. **6.6. Special handling precautions.** No special precautions. The elimination of the unused medication and of all the materials that have been in contact with it, will be carried out in accordance with local regulations. **7. MARKETING AUTHORIZATION HOLDER.** SEID, S.A. Carretera de Sabadell a Granollers, Km. 08185 .15 Lliçà de Vall (Barcelona). **8. MARKETING AUTHORIZATION NUMBER (S)** 55.868. **9. DATE OF FIRST AUTHORIZATION / RENEWAL OF AUTHORIZATION.** April 14, 1983. **10. DATE OF REVISION OF THE TEXT.** October 2003

1. Groen JW, Grosfeld S, Bramer WM, Ernst MF, Mullender MM. Cyclic and non-cyclic breast-pain: A systematic review on pain reduction, side effects, and quality of life for various treatments. Eur J Obstet Gynecol Reprod Biol. 2017 Dec; 93-219:74. **2.** Olawaiye AB, Alvero R. Mastodynia. En: Ferri FF. (ed) Ferri's Clinical Advisor 1 ,2018st Edition. pp: 800. **3.** Mauvais-Jarvis,P. La terapia hormonal de la enfermedad mamaria benigna. La lettre du gynécologue. Le Courier du spécialiste. Vol.51. Septembre 1986.

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Natural Hormones