INSTRUCTION
on medical use of
PROGESTOGEL

Composition:
active ingredient: progesterone;
1 g of gel contains 10 mg (0.01g) of progesterone;
excipients: octyldodecanol, carbomer 980, polyethoxylated hydrogenated castor oil, triethanolamine, 96% ethanol, purified water.

Pharmaceutical form. Gel for local application.

Pharmacotherapeutic group. Hormones of sexual glands and agents used in pathology of the genitals. Gestagens. ATC code G03D A04.

Clinical characteristics.
Indications. Mastodynia, benign mastopathy associated with progesterone insufficiency.

Contraindications. Increased sensitivity to any of the components of the product.

Administration and dosage.
Transdermal route. For use open the tube and punch it with a small puncheon located in the stopper. The metal membrane of the tube must be fully opened. Use a plastic applicator-dispenser for calculation of a daily dose. Press the tube above the spatula ruler. 1 dose is equal to a column (the diameter of a pencil) the length of which coincides with an indent on the ruler. One tube contains 30 doses. One dose of the applicator (2.5 g contain 25 mg of progesterone) is applied on the surface of each breast once daily (including days of menstruation). The gel is left on the site of application until complete absorption.

Side reactions. Occurrence of allergic reactions is possible.

Overdose. Overdose is unlikely due to low systemic absorption.

Use during pregnancy and breast feeding.
Progestogel may be administered to pregnant women, however, in trimesters II-III of pregnancy the product may be used only if the expected benefit from the product use overweighs the possible risk for the fetus.
It is not recommended to use the product in the period of breast feeding as the clinical data on the possibility of using Progestogel in this period is not available.

Children. The product is not used in pediatric practice due to the lack of the data.

Specifics of use. Not to exceed the recommended dose.

Capacity to influence the reaction while driving vehicles or operating machines. The data is not available.

Interaction with other medicines and other types of interaction. No clinically significant interaction was found.

Approved 13.12.2010 by UKR HA
Pharmacological properties.

Pharmacodynamics. The pharmacological properties are conditioned by the presence of progesterone which is a hormone of corpus luteum. In the breast tissue progesterone decreases permeability of capillaries and intensity of cyclic edema of connective tissue stroma, prevents proliferation and mitotic activity of the epithelium of ducts.

Pharmacokinetics. At application, the gel quickly evaporates, with 10% of the applied dose penetrating the skin. Progesterone metabolism occurs in the skin and breast. There is no systemic action.

Pharmaceutical characteristics.

Main physicochemical properties: a colorless, semitransparent, slightly opalescent gel with odor of alcohol.

Shelf life. 3 years.

Storage.
Store at a temperature not exceeding 25°C.
Keep out of the reach of children.

Package.
80 g in each tube with a screw cap together with a dosing spatula per carton pack.

Dispensing. Prescription medicine.

Manufacturer.
Besins Manufacturing Belgium, Belgium.
Laboratoires Besins International, France.

Location. 128, Groot Bijgaardenstraat, 1620 Drogenbos, Belgium.
13, rue Périer, 92120 Montrouge, France.

Date of last revision:

Complies with the materials of the registration dossier and significant data on the use of the medicinal product.