INSTRUCTIONS on use of
OXYPROGESTERONE CAPRONATE

Content:
active ingredient: 1 ml of the solution contains 125 mg of oxyprogesterone capronate (on a dry basis); excipients: benzyl benzoate, olive oil refined.

Dosage form. Oil solution for injection.


Clinical performance.
Indications. Used in case of:
– miscarriage or threatened miscarriage;
– primary and secondary amenorrhea, polymenorrhea;
– dysfunctional uterine bleeding.

Contraindications. Hypersensitivity to the components of the drug. The second half of pregnancy; extraterine pregnancy or abortion that didn’t happen (in history); liver disease (especially cirrhosis); cholestatic jaundice during pregnancy (in history); benign hyperbilirubinemia; hepatic failure; porphyria; tachycardia; neoplasms of genital organs and mammary glands; severe thrombophlebitis; thrombotic tendency.

Dosage and Administration: Warm up slightly a vial of drug in a water bath before use (30-40˚C). In the case of precipitation of crystals, warm up the ampoule in a boiling water bath until complete dissolution. Inject intramuscularly and subcutaneously.
In threatened miscarriage or miscarriage started during the first half of pregnancy, inject single dose of 125-250 mg (1-2 ml of 12.5 % solution) each week.
In primary or secondary amenorrhea inject 250 mg once or in two intakes immediately after the termination of oestrogen administration.
In dysfunctional uterine bleeding (to normalize menstrual cycle) inject 65-125 mg (0.5-1.0 ml of a 12.5 % solution) at Day 20 – 22 of the cycle.

Adverse effects.
In cardiovascular system: possible increased blood pressure.
In metabolism: possible swelling.
In digestive system: changed appetite, abdominal distension, abdominal pain, compromised liver function, jaundice, rarely (in case of prolonged use) – nausea, vomiting.
In CNS: rarely (in case of prolonged use) – headache, depression, insomnia, drowsiness, dizziness.
In endocrine system: rarely (in case of prolonged use) – increased body weight, pain and tension in mammary glands, change in vaginal discharge, irregular uterine bleeding, amenorrhea, premenstrual syndrome, decreased libido, acne, chloasma, alopecia, hirsutism, thrombembolia.
Possible allergic reactions as skin rash, urticaria, anaphylactic reactions. Changes in the injection site.

Overdose. Uninvestigated.
Administration in pregnancy or breast-feeding. The drug is used only in the first half of pregnancy. The risk of congenital abnormalities including sexual abnormalities in children of both sexes, associated with the action of exogenous progesterone during pregnancy, is not fully established. Progesterone should not be used during breast-feeding due to penetration into the breast milk.

Administration details. Caution should be used in administration the drug for patients with cardiovascular diseases, diabetes, bronchial asthma, epilepsy, migraine, depression. You should not use the drug to patients with rare hereditary diseases such as galactose intolerance, lactase deficiency, and glucose-galactose malabsorption. During treatment it is recommended to conduct regular examination, the frequency and amount of which are determined individually. In case of any progestagen-dependent tumour such as meningioma in the history and/or its progression during pregnancy or previous hormone therapy, the patients should be under close medical supervision.

Capability to influence the reaction rate in car driving or operating other mechanisms. During treatment it is necessary to avoid potentially hazardous activities requiring attention and speed of psychomotor actions.

Interaction with other drugs and other interactions. Oxyprogesteron capronate reduces the effect of drugs, which stimulate myometrium contraction (oxytocin, pituitrin), anabolic steroids (retabolil, nero lulom), and gonadotropic hormones of hypophysis. When interacting with oxytocin it decreases the lactogenic effect. Enhances the action of diuretics, antihypertensive agents, immunosuppressants, bromocriptine and system coagulants. Reduces the efficacy of anticoagulants. Changes the effects of hypoglycemic means. Gestagen activity reduces the inductors of microsomal oxidation (barbiturates, hydantoins, rifampin, etc.). The concomitant use of ß-agonists and hydroxyprogesterone capronate to prevent preterm delivery reduces the side effects of ß-agonists.

Pharmacological properties. Pharmacodynamics. Oxyprogesterone capronate is a synthetic hormone similar to the yellow body (of progesterone). According to the biological properties it is similar to progesterone: causes a transition of the mucous membrane of the uterus from proliferation phase induced by follicular hormone, to secretory phase, and after impregnation provides its transition into condition required for development of an impregnated ovum; reduces the excitability and contractility of uterus muscles, and stimulates development of terminal elements of the mammary glands. In comparison with progesterone it is more stable in the body, has a slower and more prolonged effect. After a single intramuscular injection it retains its effect from 7 to 14 days. Pharmacokinetics. Uninvestigated.

Pharmaceutical characteristics. Basic physicochemical properties: transparent oil liquid from light yellow to greenish-yellow colour.

Incompatibility. The drug should not be mixed with other drugs.

Shelf life. 5 years.

Storage conditions. Store in light protected place at a room temperature from 15˚C to 25˚C. Keep away from children.

Packing. 1 ml in the ampoule. 10 ampoules per package.

Dispensing category. Prescription only.

Manufacturer. PJSC BIOFARMA.

Location. 9, M. Amosova, str., Kyiv, 03038, Ukraine

Last revised.