1. NAME OF THE DRUG PRODUCT

GESGINAL (Progesterone Vaginal Tablets 200 mg)

Strength

Each uncoated vaginal tablet contains:
Progesterone BP 200 mg (Natural Micronized)

Pharmaceutical/Dosage form

Uncoated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative declaration

Each uncoated vaginal tablet contains:
Progesterone BP 200 mg
(Natural Micronized)

3. PHARMACEUTICAL FORM

"White coloured, elongated, biconvex, scored on one side uncoated tablets."

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Progesterone is indicated for the treatment of secondary amenorrhea, Luteal support during artificial reproductive technology, Luteal support in luteal phase defect, to promote normal menstrual periods in women who are premenopausal but have stopped having periods due to low progesterone levels. Progesterone is also used to promote embryo implantation and pregnancy in conjunction with fertility treatments in women.

4.2 Posology/Dosage and method of administration

Secondary annerrohoes Progesterone tablets may be given as a single dose of 400 mg at bedtime for 10 days. Luteal support during ART: 400 mg once day from the day of embryo transfer till pregnancy is confirmed. If pregnant, it is continued till 12th week of pregnancy. Luteal support in luteal phase defect: progesterone tablets 300 mg from 17th day of the cycle for 10 days. If pregnant, it is continued till 12th week of pregnancy. Prevention of endometrial Hyperplasia: it should be given single daily dose at bedtime, 200 mg orally for 12 days sequencially per 28-days cycl, to a postmenopausal women with a uterus who is receiving daily conjugated estrogebns tablets.

4.3 Contraindications

Progesterone is contraindicated with Hypersensitivity to the active substance or to any of the excipients, undiagnosed abnormal genital bleeding, missed abortion or ectopic pregnancy, history of breast cancer, deep vein thrombosis, pulmonary embolism, known liver dysfunction or disease.

4.4 Special warnings and precautions for use

Serious precautions are reported with progesterone including the following: Heart attacks: Discontinue use and get medical attention immediately if you experience severe pains in your chest or legs with or without shortness of breath, weakness and/or fatigue. Strokes: Discontinue use and get medical attention immediately if you experience changes in vision or speech, sudden new severe headaches, and/or vision changes. Blood clots: Discontinue use and get medical attention immediately if you experience extremity pain, tenderness, and/or a warm sensation, pain in your calf when you stretch your toes upward, and/or a pale or bluish skin discoloration. Depression: Consult with your physician if you have a history of depression or any other psychiatric disorders.

4.5 Interaction with other drug products and other forms of interaction

The metabolism of progesterone by human liver microsomes was inhibited by Ketoconazole, ketoconazole is a known inhibitor of cytochrome P450 3A4. Hence Ketoconazole and other known inhibitors of these enzymes may increase the bioavailability of the progesterone. The clinical relevance of this in-vitro finding is unknown.

4.6 Fertility, pregnancy and lactation

Pregnancy The administration of this medicine in the course of the second and third trimester of pregnancy can favour the appearance of severe cholestasis or hepatitis. So it is recommended do not use this medicine during pregnancy. Lactation Detectable amounts of the progesterone have been identified in the milk of nursing mothers, do not use this medicine by the nursing women.

4.7 Effects on ability to drive and use

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Common side effects of progesterone include the following: Headaches, Breast pain, Irregular vaginal bleeding or spotting, Abdominal cramps, Bloating, Nausea and vomiting. Hair loss, swelling of extremities, vaginal yeast infections.

4.9 Overdose

No studies on overdose have been conducted in human, in case of overdose, tablets should be discontinued and the patient should be treated symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Progesterone Hormone, ATC code: G03DA04. Mechanism of action Its contain progesterone is identical to progesterone of ovarian origin. Progesterone is lipophilic in nature and diffuse freely into cells, where they binds to the progesterone receptors and exert their progestational activity. In the presence of adequate estrogen transform a proliferative endometrium in to a secretory endometrium. Progesterone is necessary to increase endometrial receptivity for implantation of an embryo.

5.2 Pharmacokinetic properties

Absorption

The Micronized progesterone is absorbed through the digestive tract. It is a sustained release formulation of micronized progesterone. The absolute bioavailability of micronized progesterone is not known. Distribution Circulating progesterone is extensively bound to plasma proteins, especially albumin and corticosteroid binding globulin.

Biotransformation

Progesterone is metabolized primarily by the liver largely to pregnanediols and pregnanolones. Prenanediols and pregnanolones are conjugated in the liver to glucuronide and sulfate metabolites. Progesterone metabolites which are excreted in the bile may be deconjugated and may be further metabolized in the gut via reduction, dehydroxylation, and epimerization.

Elimination

The glucuronide and sulfate conjugates of pregnanediol and pregnanolone are excreted primarily in urine. A smaller quantity is excreted in bile. Progesterone metabolites which are excreted in the bile may undergo enterohepatic recycling or may be excreted in feces.

5.3 Preclinical safety data

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Starch Glycolate
Crospovidone
Maize Starch/Corn Starch
Lactose/Lactose Monohydrate
Colloidal Anhydrous Silica
Povidone
Isopropyl Alcohol
Purified Talc
Sodium Lauryl Sulphate
Sodium Stearyl Fumarate

6.2 Incompatibilities

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6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C in a dry place.

6.5 Nature and contents of container

10 tablets in blister packed and such 1 blister further packed in unit carton along with package insert.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

After successful treatment the remaining tablets should be discarded or returned to the pharmacist.

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Ignite Pharma Nigeria Limited
30, Ajegunle Village,
Magboro Ogun State, Nigeria.

8. DRUG PRODUCT MANUFACTURER

SYNOKEM PHARMACEUTICALS LIMITED

14/486, Sunder Vihar, Outer Ring Road,

Paschim Vihar, New Delhi-110 087, INDIA.

9. NAFDAC REGISTRATION NUMBER(S)

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