For the use only of Registered Medical Practitioners or a Hospital or a Laboratory.

Progesterone Injection IP 100 mg / 2 ml

AMERICAN
ConcivOn 100
Injection

FOR IM INJECTION ONLY

Composition:
Each ml contains :

Progesterone IP	50 mg
Benzyl Alcohol IP	0.1 ml
Ethyl Oleate IP q.s. to	1.0 ml

Indications:
- For the maintenance of early pregnancy in cases of documented history of repeated miscarriages due to luteal phase defect and in selected cases as an adjunct to successful treatment of infertility with techniques such as in vitro fertilization (IVF) or gamete intra-fallopian transfer (GIFT) in order to facilitate uterine implantation of the fertilized ovum.
- For Progesterone withdrawal test in endocrinal evaluation of a case of secondary amenorrhoea (where pregnancy is ruled out) to judge oestrogen priming.
- For the treatment of dysfunctional uterine bleeding.
- For threatened abortion.

Dosage and Administration:
Progesterone is administered as intramuscular injection. Progesterone injection may cause irritation at the site of injection.

Maintenance of pregnancy: The recommended dose is twice weekly or more frequent (maximum: daily) injections of 25-100 mg from approximately day 15, or day of ovum pickup onwards until 12-14 weeks of pregnancy when secretion of Progesterone from the placenta is generally well established.

Daily dosage can be increased to 200 mg at the discretion of the physician.

Progesterone withdrawal test in endocrinal evaluation of a case of secondary amenorrhoea to judge oestrogen priming: 50-100 mg/day for 3-6 consecutive days (after pregnancy is ruled out)

Dysfunctional Uterine bleeding: The recommended dose is 5-10 mg daily given for five to ten consecutive days until 2 days before anticipated onset of menstruation.

Threatened abortion: In critical patients the recommended dose is 200 mg daily. For patients who have improved clinically on 200 mg daily dose the recommended dose can be reduced to 100 mg daily. In clinically stable patients the dose should be 50/100 mg twice or thrice a week.

As the indications for Ception 100mg injection is restricted to women of childbearing age, dosage recommendations for children and the elderly are not appropriate.

Ception 100mg injection should be injected deep into the buttock, rather than thigh or deltoid, a 1.5 inch (3.8 cm) needle. This site has ample fat cells where a depot of Progesterone using can be formed for slow release.

Contraindications:
Progesterone injection is contraindicated in the following conditions:

1. Known hypersensitivity to Progesterone or any of the inactive ingredients.
2. Thrombophlebitis, current or past history of thromboembolic disorders, cerebral haemorrhage.
3. Liver dysfunction or disease.
4. Known or suspected malignancies of the breast or genital tract.
5. Undiagnosed vaginal bleeding.
6. As a diagnostic test for pregnancy.

Warnings and Precautions:
- This medication should be used cautiously in patients with conditions that might be aggravated by fluid retention (e.g. hypertension, cardiac disease, renal disease, epilepsy) diabetes, asthma and acute intermittent porphyria.
- If unexplained, sudden or gradual, partial or complete loss of vision, proptosis or diplopia, papilloedema, retinal vascular lesions or migraine occur during therapy, the drug should be discontinued and appropriate diagnostic and therapeutic measures instituted.
- Because of the occasional occurrence of thrombophlebitis and pulmonary embolism in patients taking progestogens, the physician should be alert to the earliest manifestation of the disease.
- In cases of breakthrough bleeding, as in all cases of irregular bleeding per vaginum, non-functional causes should be borne in mind. In cases of undiagnosed vaginal bleeding, adequate diagnostic measures are indicated.
- Patients who have a history of psychic depression should be carefully observed and the drug discontinued if the depression recurs to a serious degree.
- Progesterone may affect the results of laboratory tests of hepatic and/or endocrine functions.

Drug Interactions:
The metabolism of Progesterone by human liver microsomes was inhibited by Ketoconazole. Ketoconazole is a known inhibitor of Cytochrome P4503A4, and these data suggest that Ketoconazole or known inhibitors of this enzyme may increase the bioavailibility of Progesterone. Progesterone may interfere with the effects of Bromocriptine and may raise the plasma concentration of Cyclosporin.

Pregnancy & Lactation:
Pregnancy : Ception 100mg injection may be used to maintain pregnancy where there is deficient production of endogenous Progesterone from the corpus luteum. It should not be necessary to administer Ception 100mg injection once there is adequate secretion of placental Progesterone. Ception 100mg injection contains Progesterone itself, the same as the naturally secreted hormone, and there is no evidence associated with masculinization of a female foetus as are synthetic progestins.

Lactation : Detectable amounts of Progesterone have been identified in the breast milk but its effect on the nursing infant is not known. Because of the potential for tumorigenicity shown for Progesterone in animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Side effects:
The following adverse reactions have been observed in women taking Progesterone: breakthrough bleeding, spotting, change in menstrual flow, amenorrhoea, oedema, changes in weight (increase or decrease), catabolism, changes in cervical erosion and cervical secretions, breast changes, cholestatic jaundice, rash (allergic), acne, chloasma, nausea, alopecia, hirsutism, mental depression, pyrexia, insomnia, somnolence and pain, irritation, swelling and / or redness at the site of injection.

Overdosage:
This is unlikely and is not expected to produce any adverse effects. Patient should be observed and, if necessary, symptomatic and supportive measures should be provided.

Clinical Pharmacology:
Ception 100mg injection contains Progesterone, which is chemically identical to the naturally occurring Progesterone secreted by the human ovary.

Mechanism of Action:
Progesterone is lypophilic in nature and diffuses freely into cells, where it binds to the Progesterone receptors and exerts its progestational activity. The steroid-receptor complex binds to DNA in the nucleus, thereby inducing the synthesis of specific proteins.

Intramuscular injection of Progesterone transforms proliferative endometrium into secretory endometrium and inhibits the secretion of pituitary gonadotropins, which in turn prevents follicular maturation and ovulation.

Pharmacokinetics:
Owing to its low oral bioavailability, Progesterone is usually administered by intramuscular injection, or as rectal or vaginal suppositories. Progesterone is rapidly absorbed from the site of an intramuscular injection.
Intramuscular injection of 25 mg or more produces peak concentrations in the luteal range within 8 hours and concentrations are elevated for up to 48 hours; higher doses produce transient peak concentrations similar to those seen during pregnancy.
Progesterone is approximately 96-99% bound to serum proteins, primarily to serum albumin and transcortin. It is metabolized primarily by the liver largely to pregnanediols and pregnanolones, which are then conjugated in the liver to glucuronide and sulphate metabolites.
The metabolites are excreted mainly in the urine and the bile. Progesterone metabolites, which are excreted in the bile, may undergo enterohepatic recycling or a smaller quantity may be excreted in the faeces.

Incompatibilities:
None reported.

Storage:
Store below 25°C. Protect from light.
On storage, solid matter may separate. This should be redissolved by warming before use.
Keep medicine out of reach of children.

Presentation & Pack Size:
100 mg / 2 ml - 5 x 2 ml Ampoules

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