

HerNMP

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for **HerNMP** [(Progesterone Soft Gelatin Capsules 100mg, 200mg and 300mg) For Oral / Vaginal / Rectal Use] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES Progesterone is lipophilic in nature and diffuse freely into cells, where they bind to the progesterone receptors and exert their progestational activity. The steroid receptor complex binds to DNA in the nucleus, thereby inducing the synthesis of specific proteins.

INDICATION: Vaginal: - Supplementation of the luteal phase of infertility due to luteal deficiency, Correction of progesterone deficiency in case of recurrent and threatened miscarriage, Treatment of puerperal depression Oral:- Menopause , premenstrual syndrome, menstrual irregularities, benign mastopathies, premenopause , prevention of endometrial hyperplasia and Secondary amenorrhea.

DOSAGE AND ADMINISTRATION: Vaginal / rectal administration Each capsule should be deeply inserted into the vagina. Supplementation of the luteal phase in case of infertility due to luteal deficiency The dosage recommended is 400 to 600mg per day starting with the day of injection of hCG up to the 12th week of pregnancy. To help pregnancy and for the management of recurrent and threatened miscarriage The dosage recommended is 200 to 400 (max 600) mg per day in divided doses, till 12th to 14th week of pregnancy as required. Treatment of puerperal depression The dosage recommended is 200 to 400 mg per day in divided dosages for 7 days after delivery. On an average in the case of deficiency of progesterone, the dosage is from 200 to 300 mg of progesterone per day once daily or in two divided doses, one in the morning and one at night, Menopause (In addition to estrogen treatment) One capsule of 200 mg per day in the evening for the last 14 days of estrogen treatment per cycle , Premenstrual syndrome, benign mastopathies, menstrual irregularities, pre-menopause The treatment will be started at a dose of 200 mg to 300 per day, 10 days per cycle, Prevention of Endometrial Hyperplasia It should be given as a single daily dose at bedtime, 200 mg orally for 12 days sequentially per 28-day cycle Treatment of secondary amenorrhea It may be given as a single daily dose of 400 mg at bedtime for 10 days.

CONTRAINDICATION: Known, suspected, or history of breast cancer, Active deep vein thrombosis, pulmonary embolism or history of these conditions, Active arterial thromboembolic disease (for example, stroke and myocardial infarction), or a history of these conditions, Known or suspected pregnancy, Vaginal route-Undiagnosed vaginal bleeding, Oral route: Serious alterations in hepatic functions.

WARNINGS & PRECAUTIONS: An increased risk of pulmonary embolism, deep vein thrombosis (DVT), stroke, breast cancer, endometrial cancer, ovarian cancer, dementia, vision abnormalities and myocardial infarction has been reported with estrogen plus progestin therapy, increased risk of stroke, coronary heart disease and thromboembolism was reported

DRUG INTERACTIONS: Ketoconazole is a known inhibitor of cytochrome P450 3A4, hence these data suggest that ketoconazole or other known inhibitors of this enzyme may increase the bioavailability of progesterone.

ADVERSE REACTIONS: Drowsiness or giddiness , Soreness, diarrhea and flatulence may occur with rectal administration, endometrial carcinoma, hypospadias, intra-uterine death, menorrhagia, menstrual disorder, metrorrhagia, ovarian cyst, spontaneous abortion, circulatory collapse, congenital heart disease (including ventricular septal defect and patent ductus arteriosus), hypertension, hypotension, tachycardia, acute pancreatitis, cholestasis, cholestatic hepatitis, dysphagia, hepatic failure, hepatic necrosis, hepatitis, increased liver function tests (including alanine aminotransferase increased, aspartate aminotransferase increased, gamma-glutamyl transferase increased), jaundice, swollen tongue, alopecia, pruritus, urticarial, blurred vision, diplopia, and visual disturbance, aggression, convulsion, depersonalization, depressed consciousness, disorientation, dysarthria, loss of consciousness, paresthesia, sedation, stupor, syncope (with and without hypotension), transient ischemic attack, suicidal ideation, abnormal gait, anaphylactic reaction, arthralgia, blood glucose increased, choking, cleft lip, cleft palate, difficulty walking, dyspnea, face edema, feeling abnormal, feeling drunk, hypersensitivity, asthma, muscle cramp, throat tightness, tinnitus, vertigo, weight decreased and weight increased.

MARKETED BY:



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IN/ HerNMP 100,200,300mg /MAY-2016/01/ABPI
(Additional information is available on request)