HerNMP SR

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

Abbreviated Prescribing information for **HerNMP SR** [(Progesterone Sustained Release Tablets 200mg, 300mg and 400mg)] [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**: Menopause , Premenstrual syndrome, Menstrual irregularities, Benign mastopathies , Premenopause , Prevention of endometrial hyperplasia and Secondary amenorrhea. **DOSAGE AND ADMINISTRATION:- Menopause-**One tablet 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, usually from 14th day to until onset of menstruation**. 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. **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, hypospadia, 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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(Additional information is available on request)