DEVIRY 10

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

Abbreviated Prescribing information for **DEVIRY 10** [Medroxyprogesterone Acetate (MPA) Tablets I.P 10mg] [Please refer the complete prescribing information available at www.torrentpharma.com] **PHARMACOLOGICAL PROPERTIES**: Androgenic and anabolic effects have been noted, but the MPA is apparently devoid of significant estrogenic activity. While parentally administered MPA inhibits gonadotropin production, which in turn prevents follicular maturation and ovulation, available data indicate that this does not occur when the usually recommended oral dosage is given as single daily doses. **INDICATION**: MPA is indicated for Menstrual Disorders, Dysfunctional Uterine Bleeding, Secondary Amenorrhea, for diagnostic evaluation of endogenous estrogen status, Secondary amenorrhea with adequate estrogen, Secondary Amenorrhea with inadequate estrogen, Endometriosis, Postponement of Menstruation is indicated for the treatment of schizophrenia. **DOSAGE AND ADMINISTRATION**: For a) Dysfunctional Uterine Bleeding: For heavy bleeding: MPA 10mg tid for the first 7 days followed by 1 bid for the next 7 days followed by 1 OD for the next 7 days. b) Secondary Amenorrhea for diagnostic evaluation of endogenous estrogen status: MPA10 mg 2 times daily for 5 days. Withdrawal bleeding indicates adequate estrogenisation. c) Endometriosis: MPA 10 mg 1 tab to upto 5 tabs daily for 3-4 months followed by clinical evaluation. If necessary to continue for further 3 months. Treatment to be started 7 days before the anticipated date of menses. Deviry 10 mg daily till the postponement is desired. Higher dose required if treatment is started less than 7 days before the anticipated date of menses. **CONTRAINDICATION:** Medroxyprogesterone Acetate (MPA) should not be used in women with any of the following conditions: Undiagnosed abnormal genital bleeding, known, suspected, or history of cancer of the breast, active deep vein thrombosis, pulmonary embolism or a history of these conditions, known liver dysfunction or disease, missed abortion, As a diagnostic test for pregnancy, Known or suspected pregnancy. **WARNINGS & PRECAUTIONS**: An increased risk of stroke, deep vein thrombosis (DVT), pulmonary embolism, and myocardial infarction has been reported with estrogen plus progestin therapy. Significant increased risk of stroke was reported in women receiving daily conjugated estrogens (CE 0.625 mg) plus medroxyprogesterone acetate (MPA 2.5mg) compared to women receiving placebo. The use of estrogens and progestins by postmenopausal women has been reported to increase the risk of breast cancer in some studies. An increased risk of endometrial cancer has been reported with the use of unopposed estrogen therapy in women with a uterus. The estrogen plus progestin substudy of WHI reported that daily CE/MPA increased the risk of ovarian cancer. Discontinue medication pending examination if there is sudden partial or complete loss of vision, or a sudden onset of proptosis, diplopia or migraine. **DRUG INTERACTIONS**: Increased plasma HDL and HDL2 cholesterol subfraction concentrations, reduced LDL cholesterol concentration, increased triglycerides levels, Impaired glucose metabolism and laboratory results may be altered by the use of estrogen plus progestin therapy. **ADVERSE REACTIONS**: Abnormal uterine bleeding (irregular, increase, decrease), change in menstrual flow, breakthrough bleeding, spotting, amenorrhea, changes in cervical erosion and cervical secretions. Breast tenderness, mastodynia or galactorrhea. Thromboembolic disorders including thrombophlebitis and pulmonary embolism. Nausea, cholestatic jaundice. Sensitivity reactions consisting of urticaria, pruritus, edema and generalized rash have occurred. Acne, alopecia and hirsutism have been reported. Neuro-ocular lesions, for example, retinal thrombosis, and optic neuritis. Mental depression, insomnia, somnolence, dizziness, headache, nervousness. Hypersensitivity reactions (for example, anaphylaxis and anaphylactoid reactions, angioedema), rash (allergic) with and without pruritus, change in weight (increase or decrease), pyrexia, edema/fluid retention, fatigue, decreased glucose tolerance. Dysmenorrheal/pelvic pain; increase in size of uterine leiomyomata; vaginitis, including vaginal candidiasis; change in amount of cervical secretion; changes in cervical

ectropion; ovarian cancer; endometrial hyperplasia; endometrial cancer. Breast enlargement, pain, nipple discharge, fibrocystic breast changes; breast cancer. Deep and superficial venous thrombosis; myocardial infarction; stroke; increase in blood pressure. abdominal cramps, bloating; increased incidence of gallbladder disease; pancreatitis; enlargement of hepatic hemangiomas. Chloasma or melasma that may persist when drug is discontinued; erythema multiforme; erythema nodosum; haemorrhagic eruption; loss of scalp hair. Retinal vascular thrombosis, intolerance to contact lenses. migraine; chorea; mood disturbances; irritability; exacerbation of epilepsy, dementia. Reduced carbohydrate tolerance; aggravation of porphyria; arthalgias; leg cramps; changes in libido; angioedema; hypocalcaemia; exacerbation of asthma and increased triglycerides.

MARKETED BY:

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