DEVIRY-10 mg

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

Abbreviated Prescribing information for DEVIRY-10 mg [Medroxyprogesterone Acetate Tablets I.P.]
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: 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.

INDICATIONS: Indicated in the treatment of secondary amenorrhea and functional uterine bleeding to hormonal imbalance only.

DOSAGE AND ADMINISTRATION: *Dysfunctional Uterine Bleeding: For heavy bleeding:* Deviry 10 mg 1 tid for the first 7 days followed by 1 bid for the next 7 days followed by 1 OD for the next 7 days. Deviry 10 mg 1 OD should be prescribed from 16th to 25th day in the next 2 cycles. In mild to moderate bleeding. Deviry 10 mg 1 OD from 1st to 14th day of the first cycle followed by Deviry 10 mg 1 OD from 16th to 25th day in the next 2 cycles. *Secondary Amenorrhoea For diagnostic evaluation of endogenous estrogen status:* Deviry 10 mg 2 times daily for 5 days. Withdrawal bleeding indicates adequate estrogenisation. Secondary Amenorrhoea with adequate estrogen. Deviry 10 mg cyclically from days 16 through 25 for six months; then stopped and the patient re-evaluated. Secondary Amenorrhoea with inadequate estrogen. Conjugase (Conjugated estrogens 0.625 mg) on days 1 through 25 and Deviry 10 mg on days 16 through 25 followed by five days no medication. Treatment should be continued for 4-6 months. As directed by the Physician.

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, Known or suspected estrogen- or progesterone-dependent neoplasia, Active deep vein thrombosis, pulmonary embolism or a history of these conditions, Active or recent (within the past year) arterial thromboembolic disease (for example, stroke and myocardial infarction), Known liver dysfunction or disease, Missed abortion, As a diagnostic test for pregnancy, Known hypersensitivity to the ingredients in Medroxyprogesterone Acetate (MPA) tablets, Known or suspected pregnancy.

WARNINGS & PRECAUTIONS: *Cardiovascular disorders:* An increased risk of stroke, deep vein thrombosis (DVT), pulmonary embolism, and myocardial infarction has been reported with estrogen plus progestin therapy. Should any of these events occur or be suspected, estrogen plus progestin therapy should be discontinued immediately. Risk factors for arterial vascular disease (for example, hypertension, diabetes mellitus, tobacco use, hypercholesterolemia, and obesity) and/or venous thromboembolism (for example, personal history or family history of venous thromboembolism [VTE]), obesity, and systemic lupus erythematosus should be managed appropriately. *Stroke:* In the estrogen plus progestin sub-study of the Women's Health Initiative (WHI) a statistically 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 (31 versus 24 per 10,000 women-years). The increase in risk was reported after the first year and persisted. *Coronary heart disease:* In the estrogen plus progestin substudy of WHI, no statistically significant increase of CHD events (defined as non-fatal myocardial infarction [MI], silent MI or CHD death was reported in women receiving CE/MPA compared to women receiving placebo (39 versus 33 per 10,000 women-years). An increase in relative risk was reported in year one, and a trend toward decreasing relative risk was reported in years 2 through 5. *Venous thromboembolism (VTE):* In the estrogen plus progestin substudy of WHI, a statistically significant two-fold greater rate of VTE, (DVT and pulmonary embolism [PE]), was reported in women receiving daily

CE/MPA compared to women receiving placebo (35 versus 17 per 10,000 women years). *Malignant neoplasms:* Breast cancer. *Endometrial cancer:* An increased risk of endometrial cancer has been reported with the use of unopposed estrogen therapy in women with a uterus. *Ovarian cancer:* The estrogen plus progestin substudy of WHI reported that daily CE/MPA increased the risk of ovarian cancer. Dementia, and Visual Abnormalities. There are, however, possible risks that may be associated with the use of progestins with estrogens compared to estrogen-alone regimens. These include a possible increased risk of breast cancer, adverse effects on lipoprotein metabolism (lowering HDL, raising LDL) and impairment of glucose tolerance. Undiagnosed abnormal vaginal bleeding, Elevated blood pressure, Hypertriglyceridemia, Impaired liver function and past history of cholestatic jaundice, Fluid Retention, and Hypocalcemia

DRUG INTERACTIONS: Estrogen plus progestin therapy can lead to Accelerated prothrombin time, partial thromboplastin time, and platelet aggregation time, Increased thyroid-binding globulin (TBG) levels, increased circulating corticosteroid and sex steroids, Increased plasma HDL and HDL2 cholesterol and Impaired glucose metabolism.

ADVERSE REACTIONS: *Genitourinary system:* Abnormal uterine bleeding (irregular, increase, decrease), change in menstrual flow, breakthrough bleeding, spotting, amenorrhea, changes in cervical erosion and cervical secretions. *Breasts:* Breast tenderness, mastodynia or galactorrhea has been reported. *Cardiovascular:* Thromboembolic disorders including thrombophlebitis and pulmonary embolism have been reported. *Gastrointestinal:* Nausea, cholestatic jaundice. *Skin:* Sensitivity reactions consisting of urticaria, pruritus, edema and generalized rash have occurred. Acne, alopecia and hirsutism have been reported. *Eyes:* Neuro-ocular lesions, for example, retinal thrombosis, and optic neuritis. *Central nervous system:* 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.

MARKETED BY:

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IN/DEVIRY/MAR 2026/01/ABPI

(Additional information is available on request)