DEVIRY SR

For the use of a Registered Medical Practitioner

Abbreviated Prescribing information for **DEVIRY SR**

(Medroxyprogesterone Acetate Sustained Release Tablets 30mg) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: Medroxyprogesterone acetate (MPA) inhibits the production of gonadotropin, preventing follicular maturation and ovulation, which is responsible for it's ability to prevent pregnancy. This action also thins the endometrium. MPA reduces nuclear estrogen receptors and DNA synthesis in epithelial cells of the endometrium.

INDICATIONS: It is indicated for mild to moderate Endometriosis.

DOSAGE AND ADMINISTRATION: The recommended dosage is 30 mg Once a Day or as directed by physician.

CONTRAINDICATION: Medroxyprogestrone acetate 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 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 and Coronary heart disease***:** In the estrogen plus progestin substudy of the Women's Health Initiative (WHI) a statistically significant increased risk of stroke and Coronary heart disease was reported. Venous thromboembolism (VTE): The increase in VTE risk was observed during the first year and persisted. **Malignant neoplasms:** *Breast cancer***:** The use of estrogens and progestins by postmenopausal women has been reported to increase the risk of breast cancer in some studies. *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:** The absolute risk of probable dementia was 45 versus 22 cases per 10,000 women-years. It is unknown whether these findings apply to younger postmenopausal women. **Visual Abnormalities:** Discontinue medication pending examination if there is sudden partial or complete loss of vision, or a sudden onset of proptosis, diplopia or migraine. If examination reveals papilledema or retinal vascular lesions, medication should be permanently discontinued.

DRUG INTERACTIONS Aminoglutethimide administered concomitantly with Medroxyprogesterone acetate may significantly depress the bioavailability of MPA.Users of high-dose MPA should be warned about the possibility of decreased efficacy with the use of aminoglutethimide.MPA is metabolized in vitro primarily by hydroxylation via the CYP3A4. While specific drug-drug interaction studies evaluating the clinical effect of CYP3A4 inhibitors or inducers on MPA have not been conducted or

reported in the literature, physicians should consider that interactions could occur which may result in compromised efficacy. Co-administration of MPA with CYP3A4 inducers may result in decreased systemic levels of MPA whilst co-administration of MPA with CYP3A4 inhibitors may result in increased MPA levels.

ADVERSE REACTIONS: Corticoid-like effects (e.g., Cushingoid syndrome), prolonged anovulation., retinal embolism, cataract diabetic, visual impairment, nausea, vomiting, constipation, diarrhoea, dry mouth, changes in appetite, oedema, fluid retention, pyrexia, malaise, fatigue, jaundice, jaundice cholestatic, disturbed liver function, anaphylactic reaction, drug hypersensitivity, anaphylactoid reaction, angioedema, decreased glucose tolerance, increased blood pressure, liver function test abnormal, increases in white cell, increased platelet count, transient elevations of alkaline phosphatase and/or serum transaminase activities, elevations of serum calcium and potassium levels, exacerbation of diabetes mellitus, hypercalcaemia, weight fluctuation, increased appetite, muscle spasms, dizziness, headache, loss of concentration, somnolence, cerebral infarction, adrenergic-like effects (e.g., fine-hand tremors, cramps in calves at night), tremors, depression, insomnia, confusion, nervousness, euphoria, changes in libido. Some patients may complain of premenstrual-like depression while on Medroxyprogesterone acetate, glycosuria, dysfunctional uterine bleeding (irregular, increase, decrease, spotting), galactorrhoea, amenorrhoea, cervical discharge, changes in cervical excretions and secretions, uterine cervical erosion, breast tenderness, mastodynia.

MARKETED BY:

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(Additional information is available on request)