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

DEVIRY SR

1. Generic Name

Medroxyprogesterone Acetate Sustained Release Tablets 30 mg

2. Qualitative and quantitative composition

DEVIRY

Each uncoated sustained release tablet contains:

Medroxyprogesterone Acetate I.P. …….30 mg

Excipients……q .s.

The excipients used are Microcrystalline Cellulose, Starch, H.P.M.C.K4M, Mat SR Base-1, PVPK-30, Isopropyl alcohol, Magnesium Stearate, Colloidal silicon dioxide.

3. Dosage form and strength

Dosage Form: uncoated sustained release tablet

Strength: Medroxyprogesterone Acetate I.P – 30 mg

4. Clinical particulars

4.1 Therapeutic indication

It is indicated for the treatment of Mild to Moderate Endometriosis

4.2 Posology and method of administration

As directed by the Physician.

Elderly: Not applicable

Pediatric population: Not applicable

Method of administration

For oral use.

4.3 Contraindications

Medroxyprogesterone 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.

4.4 Special warnings and precautions for use

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 demonstrated after the first year and persisted.

Coronary heart disease

In the estrogen plus progestin sub study 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 demonstrated in year one, and a trend toward decreasing relative risk was reported in years 2 through 5.

In postmenopausal women with documented heart disease (n = 2,763, average age 66.7 years), in a controlled clinical trial of secondary prevention of cardiovascular disease (Heart and Estrogen/Progestin Replacement Study [HERS]), treatment with daily CE 0.625 mg/ MPA 2.5mg per day demonstrated no cardiovascular benefit. During an average follow-up of 4.1 years, treatment with CE/MPA did not reduce the overall rate of CHD events in postmenopausal women with established coronary heart disease. There were more CHD events in the CE/MPA-treated group than in the placebo group in year 1, but not during the subsequent years. Two thousand three hundred and twenty one (2,321) women from the original HERS trial agreed to participate in an open label extension of HERS, HERS II. Average follow-up in HERS II was an additional 2.7 years, for a total of 6.8 years overall. Rates of CHD events were comparable among women in the CE/MPA group and the placebo group in HERS, HERS II, and overall.

Venous thromboembolism (VTE)

In the estrogen plus progestin sub study 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).Statistically significant increases in risk for both DVT (26 versus 13 per 10,000 women-years) and PE (18 versus 8 per 10,000 women-years) were also demonstrated.

The increase in VTE risk was observed during the first year and persisted.

Malignant neoplasms

Breast cancer

The use of estrogens and progestin's by postmenopausal women has been reported to increase the risk of breast cancer in some studies. Observational studies have also reported an increased risk of breast cancer for estrogen plus progestin therapy, and a smaller increased risk for estrogen alone therapy, after several years of use. The risk increased with duration of use and appeared to return to baseline in about 5 years after stopping treatment (only the observational studies have substantial data on risk after stopping). Observational studies also suggest that the risk of breast cancer was greater, and became apparent earlier, with estrogen plus progestin therapy as compared to estrogen alone therapy. However, these studies have not found significant variation in the risk of breast cancer among different estrogens or among different estrogen plus progestin combinations, doses, or routes of administration.

The most important randomized clinical trial providing information about this issue is the Women's Health Initiative (WHI) sub study of daily conjugated estrogens (CE 0.625 mg) plus medroxyprogesterone acetate (MPA 2.5 mg).

In the estrogen plus progestin sub study of WHI, after a mean follow-up of 5.6 years, the WHI sub study reported an increased risk of breast cancer in women who took daily CE/MPA. In this sub study, prior use of estrogen alone or estrogen plus progestin therapy was reported by 26 percent of the women. The relative risk of invasive breast cancer was 1.24 (95 percent nominal confidence interval [nCI], 1.01-1.54), and the absolute risk was 41 versus 33 cases per 10,000 women-years, for estrogen plus progestin compared with placebo, respectively. Among women who reported prior use of hormone therapy, the relative risk of invasive breast cancer was 1.86, and the absolute risk was 46 versus 25 cases per 10,000 women-years, for CE/MPA compared with placebo. Among women who reported no prior use of hormone therapy, the relative risk of invasive breast cancer was 1.09, and the absolute risk was 40 versus 36 cases per 10,000 women-years, for estrogen plus progestin compared with placebo. In the same sub study, invasive breast cancers were larger and diagnosed at a more advanced stage in the CE/MPA group compared with the placebo group. Metastatic disease was rare with no apparent difference between the two groups. Other prognostic factors such as histologic subtype, grade, and hormone receptor status did not differ between the groups.

The use of estrogen plus progestin has been reported to result in an increase in abnormal mammograms requiring further evaluation. All women should receive yearly breast examinations by a health care provider and perform monthly breast self-examinations. In addition, mammography examinations should be scheduled based on patient age, risk factors, and prior mammogram results.

Endometrial cancer

An increased risk of endometrial cancer has been reported with the use of unopposed estrogen therapy in women with a uterus. The reported endometrial cancer risk among unopposed estrogen users is about 2- to 12 times greater than in nonusers, and appears dependent on duration of treatment and on estrogen dose. Most studies show no significant increased risk associated with the use of estrogens for less than 1 year. The greatest risk appears associated with prolonged use, with increased risks of 15- to 24-fold for 5 to 10 years or more. This risk has been shown to persist for at least 8 to 15 years after estrogen therapy is discontinued.

Clinical surveillance of all women using estrogen plus progestin therapy is important.

Adequate diagnostic measures, including endometrial sampling when indicated, should be undertaken to rule out malignancy in all cases of undiagnosed persistent or recurring abnormal vaginal bleeding. There is no evidence that the use of natural estrogens results in a different endometrial risk profile than synthetic estrogens of equivalent estrogen dose. Adding a progestin to estrogen therapy has been shown to reduce the risk of endometrial hyperplasia, which may be a precursor to endometrial cancer.

Ovarian cancer

The estrogen plus progestin sub study of WHI reported that daily CE/MPA increased the risk of ovarian cancer. After an average follow-up of 5.6 years, the relative risk for ovarian cancer for CE/MPA versus placebo was 1.58 (95 percent nCI, 0.77-3.24) but was not statistically significant. The absolute risk for CE/MPA was 4.2 versus 2.7 cases per 10,000 women-years.

Dementia

In the estrogen plus progestin Women's Health Initiative Memory Study (WHIMS), a sub study of WHI, a population of 4,532 postmenopausal women aged 65 to 79 years was randomized to daily conjugated estrogens (CE 0.625 mg) plus Medroxyprogesterone acetate (MPA 2.5 mg) or placebo.

After an average follow-up of 4 years, 40 women in the CE/MPA group and 21 women in the placebo group were diagnosed with probable dementia. The relative risk of probable dementia for CE/MPA versus placebo was 2.05 (95 percent CI, 1.21-3.48). The absolute risk of probable dementia for CE/MPA versus placebo 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

4.5 Drugs 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.

4.6 Use in special populations (such as pregnant women, lactating women, pediatric patients, geriatric patients etc.)

USE IN SPECIAL POPULATION

Renal Insufficiency

The pharmacokinetics of MPA in patients with varying degrees of renal insufficiency have not been investigated.

Hepatic Insufficiency

MPA is almost exclusively eliminated via hepatic metabolism. In 14 patients with advanced liver disease, MPA disposition was significantly altered (reduced elimination).

In patients with fatty liver, the mean percent dose excreted in the 24-hour urine as intact MPA after a 10 mg or 100 mg dose was 7.3% and 6.4%, respectively

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

The following events are associated with the use of progestogens including MPA:

Cardiac disorders: myocardial infarction, congestive heart failure, palpitations, tachycardia.

Endocrine disorders: corticoid-like effects (e.g., Cushingoid syndrome), prolonged anovulation.

Eye disorders: retinal embolism, cataract diabetic, visual impairment.

Gastrointestinal disorders: nausea, vomiting, constipation, diarrhoea, dry mouth.

General disorders and administration site conditions: changes in appetite, oedema, fluid retention, pyrexia, malaise, fatigue.

Hepatobiliary disorders: jaundice, jaundice cholestatic, disturbed liver function.

Immune system disorder: anaphylactic reaction, drug hypersensitivity, anaphylactoid reaction, angioedema.

Investigations: 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.

Metabolic and nutritional disorders: exacerbation of diabetes mellitus, hypercalcaemia, weight fluctuation, increased appetite.

Musculoskeletal and connective tissue disorders: muscle spasms.

Nervous system disorders: dizziness, headache, loss of concentration, somnolence, cerebral infarction, adrenergic-like effects (e.g. fine-hand tremors, cramps in calves at night), tremors.

Psychiatric disorders: depression, insomnia, confusion, nervousness, euphoria, changes in libido. Some patients may complain of premenstrual-like depression while on Medroxyprogesterone acetate.

Renal and urinary system disorders: glycosuria.

Reproductive system and breast disorders: dysfunctional uterine bleeding (irregular, increase, decrease, spotting), galactorrhoea, amenorrhoea, cervical discharge, changes in cervical excretions and secretions, uterine cervical erosion, breast tenderness, mastodynia.

The use of estrogens and progestogens by post-menopausal women has been associated with an increased risk of breast cancer

Reporting of suspected adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: https://torrentpharma.com/index.php/site/info/adverse_event_reporting

By reporting side effects, you can help provide more information on the safety of this medicine

4.9 Overdose

In animals Deviry-SR has been shown to be capable of exerting an adreno-corticoid effect, but this has not been reported in the human, following usual dosages. The oral administration of Deviry-SR at a rate of 100 mg per day has been shown to have no effect on adrenal function.

Symptoms

Oral doses up to 3 g per day have been well tolerated. Patients receiving pharmacological doses of MPA for treatments of neoplasms (400 mg/day or greater) may occasionally exhibit effects resembling those of glucocorticoid excess.

As with the management of any over dosage, the physician should carefully observe the patient for the potential side effects. Overdose treatment is symptomatic and supportive.

5. Pharmacological properties

Medroxyprogesterone acetate (MPA) administered orally or parentally in the recommended doses to women with adequate endogenous estrogen, transforms proliferative into secretory endometrium. Androgenic and anabolic effects have been noted, but the drug 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.

5.1 Mechanism of Action

Pharmacotherapeutic group: Progestogens – Pregnen (4) derivatives, ATC code: G03DA02

Medroxyprogesterone acetate has actions and uses similar to those of progesterone.

MPA has minimal androgenic activity compared to progesterone and virtually no oestrogenic activity.

Progestogens are used in the treatment of dysfunctional uterine bleeding, secondary amenorrhea and endometriosis.

5.2 Pharmacokinetic properties

Medroxyprogesterone Acetate

Pharmacokinetics

MPA is rapidly absorbed from the G-I tract with a single oral dose of 10-250 mg. The time taken to reach the peak serum concentration (Tmax) was 2-6 hours and the average peak serum concentration (Cmax) was 13-46.89 mg/ml.

Unmetabolised MPA is highly plasma protein bound. MPA is metabolised in the liver.

MPA is primarily metabolised by faecal excretion as glucuronide conjugated metabolite.

Metabolised MPA is excreted more rapidly and in a greater percentage following oral doses than after aqueous intramuscular injection

A. Absorption:

No specific investigation on the absolute bioavailability of MPA in humans has been conducted. MPA is rapidly absorbed from the gastrointestinal tract, and maximum MPA concentrations are obtained between 2 to 4 hours after oral administration. Administration of DEVIRY-SR with food increases the bioavailability of MPA. A 10 mg dose of DEVIRY-SR, taken immediately before or after a meal, increased MPA Cmax (50 to 70%) and AUC (18 to 33%). The half-life of MPA was not changed with food.

B. Distribution:

MPA is approximately 90% protein bound, primarily to albumin; no MPA binding occurs with sex hormone binding globulin.

C. Metabolism:

Following oral dosing, MPA is extensively metabolized in the liver via hydroxylation, with subsequent conjugation and elimination in the urine.

D. Excretion:

Most MPA metabolites are excreted in the urine as glucuronide conjugates with only minor amounts excreted as sulfates.

Paediatric population

No pharmacokinetic data are available in the paediatric population.

6 Nonclinical properties

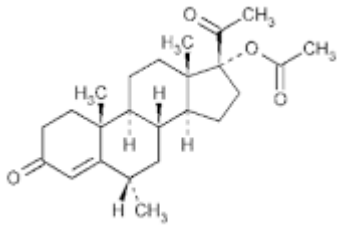
6.1 Animal Toxicology or Pharmacology

No relevant data.

7 Description

Medroxyprogesterone Acetate

Medroxyprogesterone Acetate is 6α-methyl-3, 20-dioxo-pregn-4-en-17α-yl acetate having molecular weight of 386.5 and empirical formula of C24H34O4 and the chemical structure is:



Product Description:

DEVIRY_SR white to off White Coloured, Round, Biconvex, Uncoated Tablets, Plain On Both Sides.

Other inactive ingredients are Microcrystalline Cellulose, Starch, H.P.M.C.K4M, Mat SR Base-1, PVPK-30, Isopropyl alcohol, Magnesium Stearate, Colloidal silicon dioxide.

8 Pharmaceutical particulars

8.1 Incompatibilities

No incompatibility study have been found

8.2 Shelf-life

Do not use later than the date of expiry.

8.3 Packaging information

10 tablets packed in an Alu-Alu blister.

8.4 Storage and handing instructions

Store at a temperature not exceeding 30 ˚c,

Protected from light and moisture.

9 Patient Counselling Information

Package leaflet: Information for the user

DEVIRY_SR

Medroxyprogesterone Acetate Tablets I.P.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

9.1 What DEVIRY_SR is and what it is used for

- Deviry SR contains the active substance medroxyprogesterone acetate, which is one of a group of medicines called 'progestogens'. Progestogens are similar to the natural female hormone, progesterone.
- Deviry SR has several uses. You can take Deviry SR to treat or manage:
    - Heavy periods
    - Painful periods
    - Irregular periods or periods that are more frequent than normal
    - Absence of periods
    - Mild to moderate endometriosis (where tissue from your womb is found outside your womb)

You must talk to a doctor if you do not feel better or if you feel worse.

9.2 What you need to know before you use DEVIRY_SR

Deviry-SR may not be suitable for all women. Please read the following list carefully to see if any of these apply to you. Consult your doctor if you are not sure.

Do not take Deviry-SR if you: •

- Are allergic to medroxyprogesterone acetate or other similar hormone medicines, or to any of the other ingredients of this medicine (listed in section 6).
- Are pregnant, or think you might be pregnant. Your doctor may give you a pregnancy test before starting treatment or if you miss a period during treatment.
- Have now or have had in the past breast cancer
- Have now or have had in the past blood clots forming in your veins (venous thrombosis)
- Have now or have had in the past blood clots forming in your arteries (arterial thrombosis)
- Have liver problems
- Have porphyria where your body lacks the ability to correctly produce certain enzymes and it manifests with either neurological complications or with skin problems (or occasionally both)

Warnings and precautions

1. *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.

a. 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 demonstrated after the first year and persisted.

b. Coronary heart disease

In the estrogen plus progestin sub study 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 demonstrated in year one, and a trend toward decreasing relative risk was reported in years 2 through 5.

In postmenopausal women with documented heart disease (n = 2,763, average age 66.7 years), in a controlled clinical trial of secondary Prevention of cardiovascular disease (Heart and Estrogen/Progestin Replacement Study [HERS]), treatment with daily CE 0.625 mg/ MPA 2.5mg per day demonstrated no cardiovascular benefit. During an average follow-up of 4.1 years, treatment with CE/MPA did not reduce the overall rate of CHD events in postmenopausal women with established coronary heart disease. There were more CHD events in the CE/MPA-treated group than in the placebo group in year 1, but not during the subsequent years. Two thousand three hundred and twenty one (2,321) women from the original HERS trial agreed to participate in an open label extension of HERS, HERS II. Average follow-up in HERS II was an additional 2.7 years, for a total of 6.8 years overall. Rates of CHD events were comparable among women in the CE/MPA group and the placebo group in HERS, HERS II, and overall.

c. Venous thromboembolism (VTE)

In the estrogen plus progestin sub study 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).

Statistically significant increases in risk for both DVT (26 versus 13 per 10,000 women-years) and PE (18 versus 8 per 10,000 women-years) were also demonstrated.

The increase in VTE risk was observed during the first year and persisted.

2. Malignant neoplasms

a. Breast cancer

The use of estrogens and progestins by postmenopausal women has been reported to increase the risk of breast cancer in some studies. Observational studies have also reported an increased risk of breast cancer for estrogen plus progestin therapy, and a smaller increased risk for estrogen alone therapy, after several years of use. The risk increased with duration of use and appeared to return to baseline in about 5 years after stopping treatment (only the observational studies have substantial data on risk after stopping). Observational studies also suggest that the risk of breast cancer was greater, and became apparent earlier, with estrogen plus progestin therapy as compared to estrogen alone therapy. However, these studies have not found significant variation in the risk of breast cancer among different estrogens or among different estrogen plus progestin combinations, doses, or routes of administration.

The most important randomized clinical trial providing information about this issue is the Women's Health Initiative (WHI) sub study of daily conjugated estrogens (CE 0.625 mg) plus medroxyprogesterone acetate (MPA 2.5 mg). In the estrogen plus progestin substudy of WHI, after a mean follow-up of 5.6 years, the WHI sub study reported an increased risk of breast cancer in women who took daily CE/MPA. In this sub study, prior use of estrogen alone or estrogen plus progestin therapy was reported by 26 percent of the women. The relative risk of invasive breast cancer was 1.24 (95 percent nominal confidence interval [nCI], 1.01-1.54), and the absolute risk was 41 versus 33 cases per 10,000 women-years, for estrogen plus progestin compared with placebo, respectively. Among women who reported prior use of hormone therapy, the relative risk of invasive breast cancer was 1.86, and the absolute risk was 46 versus 25 cases per 10,000 women-years, for CE/MPA compared with placebo.

Among women who reported no prior use of hormone therapy, the relative risk of invasive breast cancer was 1.09, and the absolute risk was 40 versus 36 cases per 10,000 women-years, for estrogen plus progestin compared with placebo. In the same sub study, invasive breast cancers were larger and diagnosed at a more advanced stage in the CE/MPA group compared with the placebo group. Metastatic disease was rare with no apparent difference between the two groups. Other prognostic factors such as histologic subtype, grade, and hormone receptor status did not differ between the groups. The use of estrogen plus progestin has been reported to result in an increase in abnormal mammograms requiring further evaluation. All women should receive yearly breast examinations by a health care provider and perform monthly breast self-examinations. In addition, mammography examinations should be scheduled based on patient age, risk factors, and prior mammogram results.

9.3 How to use DEVIRY_SR

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The number of tablets will depend on the condition you are being treated for. This information can also be found on the label on the box the tablets come in. The following information will help you see what the usual dose is for a particular problem.

If you do not have a period after you finish a course of Deviry-SR, check with your doctor in case you are pregnant.

If you forget to take Deviry-SR

Take the tablet as soon as you remember, and carry on taking the tablets at the normal times.

Do not take a double dose to make up for a forgotten dose.

If you take more Deviry-SR than you should

If you take too many tablets, contact your doctor straight away.

If you stop taking Deviry-SR

Do not stop taking your medicine or alter the dose you are currently taking without seeing your doctor first. It is important to keep taking your medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

9.4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Reasons for stopping Deviry-SR treatment immediately

Rarely, Deviry-SR may cause a severe allergic reaction which can be life-threatening in some cases. You can get some or all of the following symptoms: wheezing, difficulty breathing, feeling faint, and swelling of the face or tongue, hands and feet, intense itchy skin rash. If you think you are reacting badly to the medicine, get emergency medical help immediately.

If you get any of the following symptoms, you should stop taking the tablets and see your doctor immediately.

These are symptoms of a blood clot in the lungs which may all occur together:

- Sudden, severe, sharp pain in your chest
- Coughing up blood
- You suddenly become short of breath
- Your heart beats more rapidly

These can be symptoms of a blood clot in the brain ('a stroke'):

- You have an unusually severe or long headache
- Your sight is affected in any way
- You find it difficult to speak
- You collapse or faint
- Any part of your body feels weak or numb

These are symptoms of a deep-vein thrombosis (DVT):

- You have severe pain, tenderness or swelling in your calf, ankle or foot
- You have purple discolouration of the skin of the leg or the skin becomes red and warm to touch

Tell your doctor if you get any other side effects reported with Deviry-SR which may include the following:
Very common: may affect more than 1 in 10 people

- headache
- feeling sick
- unexpected or unusual vaginal bleeding or spotting

Common: may affect up to 1 in 10 people

- severe allergic reaction to the drug (e.g. wheezing, difficulty breathing)
- depression
- difficulty sleeping
- nervousness
- dizziness
- hair loss
- acne
- nettle rash or hives
- itchy skin
- vaginal discharge
- breast pain
- breast tenderness
- fever
- tiredness
- weight increase

Uncommon: may affect up to 1 in 100 people

- Facial hair growth
- milky discharge from the breast when not pregnant or breastfeeding
- oedema/fluid retention

Not known: frequency cannot be estimated from the available data

- severe allergic reaction (anaphylactic reaction)
- swelling in face/throat which may cause difficulty breathing
- delayed egg release with longer menstrual cycle (periods)
- drowsiness
- swelling in the veins due to blood clots
- tenderness or swelling in your calf, ankle or foot
- rash
- stopping or extended break of your periods
- abnormality of cervix
- decreased sugar tolerance
- weight decrease

Reporting of suspected adverse reactions

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at: https://torrentpharma.com/index.php/site/info/adverse_event_reporting

By reporting side effects, you can help provide more information on the safety of this medicine.

9.5 How to store DEVIRY_SR

Keep this medicine out of the sight and reach of children.

Deviry-SR tablets should not be used after the expiry date which is stated on the carton, blister strip or bottle label after EXP. The expiry date refers to the last day of that month.

For the blister and carton presentation, do not store your tablets above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

9.6 Contents of the pack and other information

DEVIRY SR is available in blister pack of 10 Tablets.

The active substance is Medroxyprogesterone Acetate

OTHER INACTIVE INGREDIENTS are LACTOSE , STARCH , MAGNESIUM STEARATE, POLYVINYL PYRROLIDONE, SODIUM STARCH GLYCOLLATE, COLLOIDAL SILICON DIOXIDE (AEROSIL), STARCH, LAKE OF TARTRAZINE, HYDROXY PROPYL METHYL CELU, TALC, TITANIUM DIOXIDE, PEG -6000.

10 Details of manufacture

Manufactured by:

SYNOKEM PHARMACEUTICAL LTD.

Plot No.: 56-57, Sector-6A, I.I.E (SIDCUL),

Ranipur (BHEL), Haridwar-249403, (Uttarakhand)

11 Details of permission or licence number with date

Mfg. Licence No: 27/UA/SC/P-2018 Issued on 30.12.2021

12 Date of revision

NA

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/DEVIRY_SR 30 mg/Feb-2023/01/PI