PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DEPO-PROVERA® 150 injection

Medroxyprogesterone acetate

Sugar free

Read all of this leaflet carefully before you are given DEPO-PROVERA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DEPO-PROVERA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DEPO-PROVERA is and what it is used for

DEPO-PROVERA is a progestin hormone that acts on your ovaries and the womb, and makes pregnancy less likely to occur.

- Endometriosis (a condition resulting from the appearance of endometrial tissue outside the uterus and causing pelvic pain)
- As a contraceptive to prevent you from becoming pregnant
- In the treatment of endometrial cancer (cancer of the lining of the womb)
- In the treatment of renal cancer (cancer of the kidney(s) in men and women)

2. What you need to know before you are given DEPO-PROVERA

DEPO-PROVERA should not be administered to you:

- if you are hypersensitive (allergic) to medroxyprogesterone acetate or any of the other ingredients of DEPO-PROVERA (listed in section 6)
- if you have unexplained vaginal bleeding
- if you have unexplained blood in your urine
- if you have unexplained abnormalities with your breast(s)
- if you have, or have previously had inflammation of the veins (thrombophlebitis)
- if you have liver problems
- if you are, or think you may be pregnant
- if you have known or suspected breast cancer
- if you have depression which is not well controlled with treatment
- if you have had depression with previous use of hormonal contraception

Warnings and precautions

Tell your doctor or other health care provider before being given the injection:

- if you have risk factors for osteoporosis including bone disease, excessive alcohol and/or tobacco use, a low body mass index (BMI) or eating disorder (e.g., anorexia or bulimia), strong family history of osteoporosis or chronic use of medicines that can reduce bone mass density such as anti-epileptics (used for seizures) or steroids
- if you have a history of blood clots (e.g., in your lungs or your veins); tell your health care provider immediately if you experience signs of a blood clot such as pain, swelling and redness along a vein when using DEPO-PROVERA
- if you have a history of problems with the blood vessels or nerves in your eyes; tell your health care provider immediately if you experience a sudden change in your vision (blurry vision or a partial or complete loss of vision) when using DEPO-PROVERA
- if you have a history of abnormal or unexpected vaginal bleeding as you may need additional examination or testing before using DEPO-PROVERA
- if you are on treatment for depression

- if you have had depression with previous use of hormonal contraceptives
- if you have a substance abuse problem
- if you have an underlying psychiatric disorder such as post-traumatic stress disorder or bipolar disorder
- if you have a family history of mental disorders
- if you have a history of physical or sexual abuse
- if you suffer from diabetes as DEPO-PROVERA may cause higher than normal blood glucose (sugar) levels
- if you have a condition that may be affected by weight gain or fluid retention as DEPO-PROVERA may cause these conditions to worsen (e.g., epilepsy, migraine, asthma or problems with your heart or kidneys)

Before starting treatment with DEPO-PROVERA, you should undergo a complete medical examination that may include your blood pressure, breasts, abdominal and pelvic organs and a pap smear.

Hormonal contraceptives, including DEPO-PROVERA, may cause mood changes and depression, which may be severe. Severe depression is associated with a higher risk of suicidal thoughts/behavior (e.g. talking about suicide, withdrawing from social contact, having mood swings, being preoccupied with death or violence, feeling hopeless about a situation, increasing use of alcohol/drugs, doing self-destructive things, personality changes) and suicide. If you experience mood changes and depression, contact your doctor for advice.

The use of DEPO-PROVERA may cause a decrease in the amount of calcium and other minerals in your bones. This can increase risk of developing brittle bones (osteoporosis) which can lead to bone breakages in later life. Your health care provider will assess this risk before giving you DEPO-PROVERA and if you continue using DEPO-PROVERA for more than 2 years. it is recommended that you have adequate calcium and vitamin D intake while using DEPO-PROVERA.

It is important to be aware that your menstrual cycle may be disrupted during treatment with DEPO-PROVERA and up to 28 months following your last injection. At the beginning of your treatment, DEPO-PROVERA may cause irregular bleeding and spotting. This usually decreases until complete absence of any bleeding, as such, the onset of the menopause may be missed. Discuss with your doctor if you experience any abnormal vaginal bleeding.

The results of some laboratory tests may be affected if you are using DEPO-PROVERA. It is important to tell the health care provider you are using DEPO-PROVERA if any medical tests and/or samples are being taken.

DEPO-PROVERA does not protect against sexually transmitted infections (STIs) including HIV infection (AIDS). Using DEPO-PROVERA as directed will not expose you to STIs as it is a sterile injection product. Practising safe sex (i.e. using condoms) can lower the risk of STI transmission, including HIV, through sexual contact.

Other medicines and DEPO-PROVERA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or health care provider if you are taking a medicine called aminoglutethimide (medicine used to treat Cushing's syndrome and certain breast and prostate cancers) as this may affect the way DEPO-PROVERA works.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine.

DEPO-PROVERA should not be used if you are pregnant or intend to become pregnant. DEPO-PROVERA may cause harmful effects to the unborn child including low birth weight.

Driving and using machines

It is not always possible to predict to what extent DEPO-PROVERA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DEPO-PROVERA affects them.

DEPO-PROVERA contains m**ethyl parahydroxybenzoate and propyl parahydroxybenzoate**

DEPO-PROVERA contains the excipients methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed), and exceptionally, bronchospasm.

3. How to use DEPO-PROVERA

You will not be expected to give yourself DEPO-PROVERA. It will be given to you by a person who is qualified to do so.

DEPO-PROVERA is an intramuscular injection (injected into the muscle) and will be administered by your doctor, nurse or other health care provider. DEPO-PROVERA should be shaken well immediately before use.

Endometriosis

The recommended dose is 50 mg weekly or 100 mg every 2 weeks for at least 6 months.

Contraception

The recommended dose is 150 mg every three months.

Your first injection of DEPO-PROVERA should be given during the first 5 days after the onset of your menstrual period, within 5 days after giving birth if not breastfeeding, or, if exclusively breastfeeding, at or after the sixth week after giving birth to reduce risk that you are pregnant.

If the time period since your last injection is more than 13 weeks, your health care provider will need to confirm that you are not pregnant before you are given another injection.

Consult with your health care provider when switching from other methods of birth control (e.g. oral contraceptive pill) to ensure correct timing of the first DEPO-PROVERA injection to provide continuous birth control coverage.

Endometrial and renal cancer

The recommended dose is 400 mg to 1 000 mg per week. If improvement is noted within a few weeks or months and the disease appears stabilised, the dosage may be adjusted by your doctor.

Your doctor will tell you how long your treatment with DEPO-PROVERA will last. Do not stop treatment early.

If you have the impression that the effect of DEPO-PROVERA is too strong or too weak, tell your doctor or pharmacist.

If you receive more DEPO-PROVERA than you should

Since a health care provider will administer DEPO-PROVERA, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you missed a dose of DEPO-PROVERA

Since a health care provider will administer DEPO-PROVERA, it is unlikely that the dose will be missed. Do not receive a double dose to make up for forgotten individual doses.

4. Possible side effects

DEPO-PROVERA can have side effects.

Not all side effects reported for DEPO-PROVERA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DEPO-PROVERA, please consult your health care provider for advice.

If any of the following happens, stop taking DEPO-PROVERA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- sudden skin rash or itching (especially affecting the whole body), swelling of the face, lips, tongue or throat, wheezing or difficulty in breathing

These are all very serious side effects. If you have them, you may have had a serious reaction to DEPO-PROVERA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

When used for contraception

Frequent side effects

- nervousness
- decreased sex drive

- inability to reach orgasm
- depression
- difficulty sleeping
- headache
- dizziness
- hot flushes
- abdominal pain
- abdominal discomfort
- bloating
- nausea
- rash
- acne
- hair loss
- backache
- leg cramps
- irregular and/or increased/decreased menstrual bleeding or spotting
- absence of menstrual period
- vaginal discharge
- breast pain
- breast tenderness
- painful menstruation
- pelvic pain
- inflammation of the vagina
- fluid retention
- feeling weak
- extreme tiredness
- increased or decreased weight

Less frequent side effects

- swelling under the skin, especially around face, throat, limbs or genitals

- extended lack of ovulation
- seizures (fits)
- drowsiness/sleepiness
- blood clots (e.g. in the lungs or veins) or inflammation of the veins
- diarrhoea
- yellowing of the skin or whites of the eyes (jaundice)
- liver disorder
- excessive hair growth
- itching
- hives
- muscle cramps
- joint pain
- muscle spasms
- milky discharge from the breasts not as a result of pregnancy or breastfeeding
- changes to the lining of the cervix causing pain, bleeding or discharge
- changes in male or female characteristics
- fever
- injection site reactions including pain, lumps or change in skin colour
- decreased glucose tolerance
- decreased bone mineral density

Frequency not known

- severe depression with a higher risk of suicidal thoughts/behaviour and suicide
- loss of fat tissue
- osteoporosis (decrease in bone strength) including osteoporotic fractures
- injection site reactions including persistent indentation or dimpling, lump or nodule at site of injection
- pain or tenderness at site of injection

When used for cancer

Frequent side effects

- increased weight
- tremors
- increased sweating
- swelling of feet and ankles
- fluid retention

Less frequent side effects

- rounded appearance of the face ('moon-face')
- inflammation of the veins
- irregular and/or increased/decreased menstrual bleeding or spotting
- fever

Frequency not known

- osteoporosis (decrease in bone strength) including osteoporotic fractures
- abnormal liver function test
- severe depression with a higher risk of suicidal thoughts/behaviour and suicide
- loss of fat tissue
- injection site reactions including pain or tenderness at site of injection, persistent indentation or dimpling, lump or nodule at site of injection

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DEPO-PROVERA.

5. How to store DEPO-PROVERA

- Store all medicines out of reach of children.

- Store at or below 30 °C.
- Do not refrigerate or freeze.
- Store vial upright.

6. Contents of the pack and other information

What DEPO-PROVERA contains

- The active substance is medroxyprogesterone acetate. Each mL of DEPO-PROVERA contains 150 mg medroxyprogesterone acetate.
- The other ingredients are polysorbate 80, methyl parahydroxybenzoate (0,14 % m/v), propyl parahydroxybenzoate (0,015 % m/v), macrogol 3350, sodium chloride, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and water for injection.

What DEPO-PROVERA looks like and contents of the pack

White to off-white injectable suspension.

DEPO-PROVERA 150 is available as a single dose 2 mL vial or as packs of 25 single dose 2 mL vials.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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