

MEDROXYPROGESTERONE

SAYANA PRESS
104 mg/ 0.65 mL
Suspension for Subcutaneous (SC) Injection



1.0 NAME OF THE PRODUCT

Medroxyprogesterone Acetate

2.0 DESCRIPTION OF THE PRODUCT

Medroxyprogesterone acetate (Sayana Press) Suspension for Subcutaneous (SC) Injection is a white to off-white suspension presented in a prefilled single use injection system.

3.0 WHAT IS IN THE MEDICINE?

This medicine contains medroxyprogesterone acetate (MPA), which is one of a group of medicines called 'Progestogens'. It is similar to (but not the same as) the natural hormone, progesterone that is produced in the ovaries during the second half of your menstrual cycle.

4.0 STRENGTH OF THE MEDICINE

Medroxyprogesterone acetate (Sayana Press) Suspension for Subcutaneous (SC) Injection: Each 0.65 mL contains 104 mg of medroxyprogesterone acetate (MPA). It also contains: Methyl Parahydroxybenzoate, Propyl Parahydroxybenzoate, Sodium Chloride, Polyethylene Glycol, Polysorbate 80, Monobasic Sodium Phosphate, Disodium Phosphate Dodecahydrate, Methionine, Povidone and Sodium Hydroxide or Hydrochloric acid.

5.0 WHAT IS THIS MEDICINE USED FOR?

Medroxyprogesterone acetate (Sayana Press) can be used for:

Contraception

To prevent pregnancy.

Gynecology

Management of endometriosis-associated pain.

What does this medicine do to the body?

Medroxyprogesterone acetate (Sayana Press) acts by preventing an egg from fully developing and being released from the ovaries during your menstrual cycle. If an egg is not released it cannot become fertilized by sperm and result in pregnancy. It also thickens the mucus at the entrance of the womb, making it more difficult for sperm to enter.

Medroxyprogesterone acetate (Sayana Press) also decreases serum estradiol levels and directly acts on the lesions of endometriosis, that are likely to be responsible for effect on endometriosis-associated pain.

6.0 HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

This medicine will be given to you by your doctor or healthcare professional.

Medroxyprogesterone acetate (Sayana Press) should be vigorously shaken before use to ensure that the dose being administered represents a uniform suspension.

Contraception

Medroxyprogesterone acetate (Sayana Press) is given every 3 months (12-14 weeks) as a single subcutaneous injection into the anterior thigh or abdomen. Dosage does not need to be adjusted for body weight.

Self-injection:

Medroxyprogesterone acetate (Sayana Press) 104 mg/0.65 mL pre-filled single dose injector may be administered by a healthcare professional (HCP) or, when considered appropriate by the HCP, self-injected by the patient.

INSTRUCTIONS FOR USE

For Subcutaneous Injection Only

SAYANA[®] PRESS can be given by a healthcare provider or by the patient.

Introduction

Sayana Press is a disposable injector that contains a single dose of medicine sealed in a reservoir. These instructions show step-by-step how to prepare and give the injection.

Storage

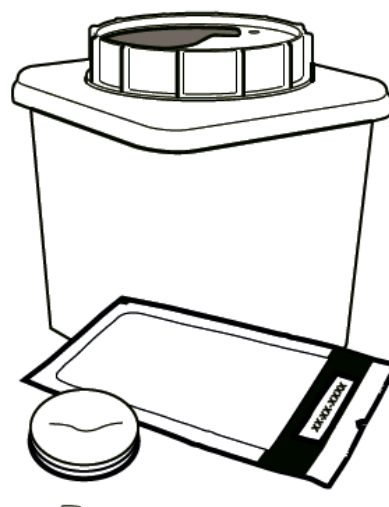
See section 14.0 **How should you keep this medicine.**

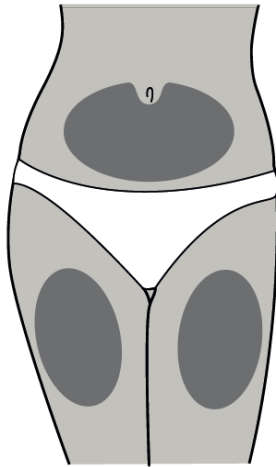
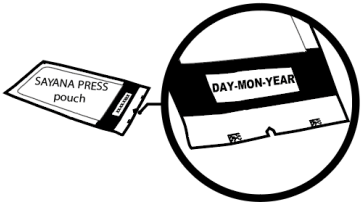
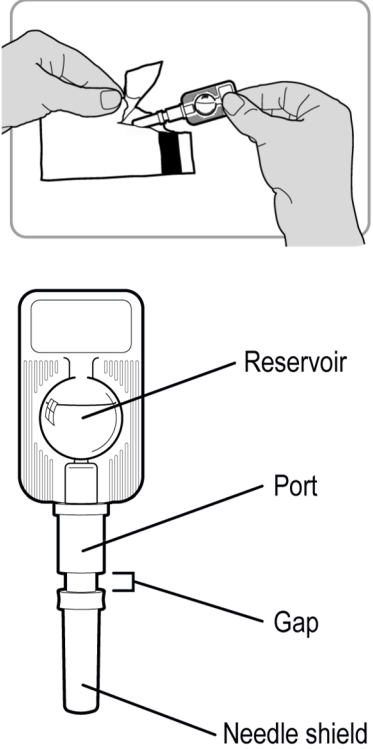
Do not use SAYANA PRESS after the expiry date stated on the injector, foil pouch and carton. Always keep out of sight and reach of children.

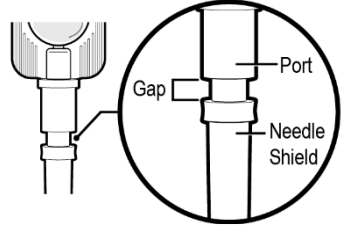
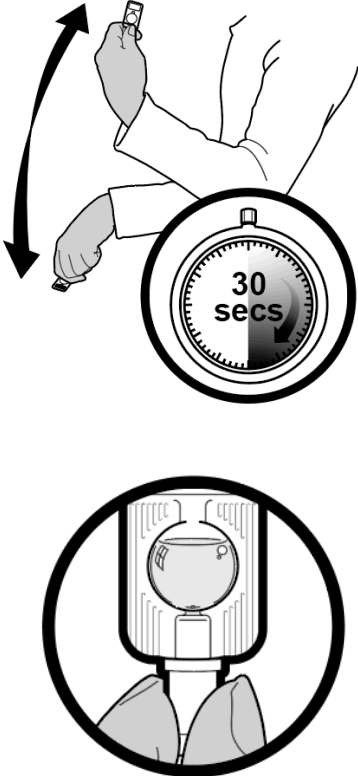
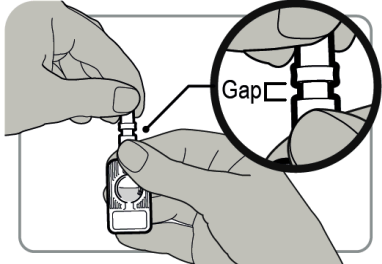
Gather your supplies

Gather the following supplies on a clean flat surface:

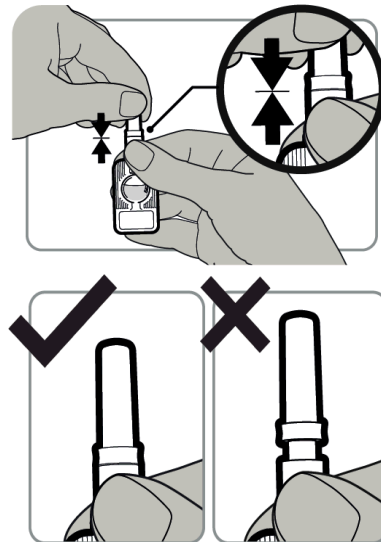
- A SAYANA PRESS injector (in its sealed foil pouch).
- A suitable container for the used injector.
- A clean cotton pad or clean paper tissue.



<p>Step 1: Select and clean injection area</p> <ul style="list-style-type: none"> • Wash and dry your hands thoroughly before starting. • Choose a suitable area for the injection, either the abdomen (belly) or the front upper thigh. <ul style="list-style-type: none"> ○ <u>Do not</u> inject into bony areas or close to the navel (belly button). ○ <u>Do not</u> inject into skin that is scarred or where there are skin conditions such as eczema or psoriasis. • Change the injection site for each new injection. • Clean the area of skin as instructed by your Healthcare provider. 	
<p>Step 2: Prepare for use</p> <ul style="list-style-type: none"> • Check that the pouch is not open or does not appear to be damaged. • Check that the expiry date has not passed. <p>Ensure that the pouch is at room temperature below 30°C.</p>	 <p>Check expiry date and tear notch</p>
<p>Step 3: Remove injector from pouch</p> <ul style="list-style-type: none"> • Carefully tear open the foil pouch at the tear notch. <p>Take out the injector.</p> <ul style="list-style-type: none"> ○ <u>Do not</u> remove the needle shield from the injector yet. 	

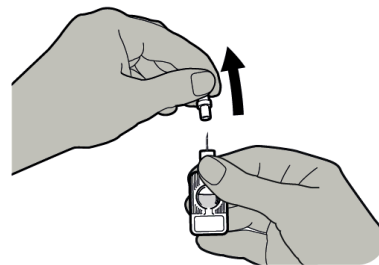
<p>Step 4: Check the injector</p> <ul style="list-style-type: none"> • Check the injector. There should be a gap between the needle shield and the port. <ul style="list-style-type: none"> ○ Discard the injector and use a new one if: <ul style="list-style-type: none"> • there is no gap • the injector is damaged • the needle shield has come off, or is missing. 	 <p>The diagram shows a close-up of the injector's port and needle shield. A circular inset highlights the area where the needle shield meets the port, with a label 'Gap' pointing to the space between them. Other labels include 'Port' and 'Needle Shield'.</p>
<p>Step 5: Mix the medicine and Check the medicine</p> <ul style="list-style-type: none"> • Hold the injector firmly by the port. • Shake the injector vigorously for at least <u>30 seconds</u> to mix the medicine. • After shaking, check the medicine in the reservoir. It should appear evenly white. <ul style="list-style-type: none"> ○ Discard the injector and use a new one if: <ul style="list-style-type: none"> • the medicine is not white and uniform • the medicine is leaking <p>If there is any delay before injecting, you must repeat the mixing step.</p>	 <p>The top diagram shows a hand holding the injector by the port, with a curved arrow indicating a vigorous shaking motion. Below this is a circular inset showing a stopwatch face with '30 secs' and a checkmark, indicating the required mixing time. The bottom diagram shows a close-up of the injector's reservoir, which is filled with a white, uniform liquid.</p>
<p>Step 6: Activate the injector</p> <ul style="list-style-type: none"> • Hold the injector firmly by the port with one hand. • Make sure the needle shield is pointing upwards. <ul style="list-style-type: none"> ○ <u>Do not</u> squeeze the reservoir. 	 <p>The diagram shows a hand holding the injector by the port. A circular inset shows a close-up of the needle shield being moved upwards, with a label 'Gap' pointing to the space between the shield and the port.</p>

- Hold the needle shield with the other hand.
- Push the needle shield firmly towards the port until it will go no further.
- Confirm there is no gap remaining. This means you have activated the injector correctly.



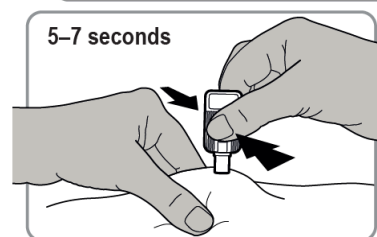
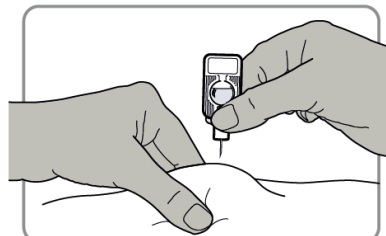
Step 7: Remove the needle shield

When you are ready to inject yourself pull the needle shield off.

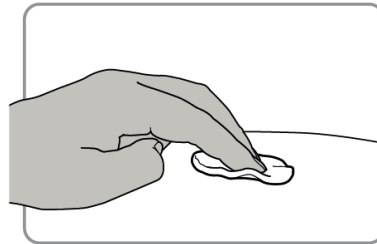
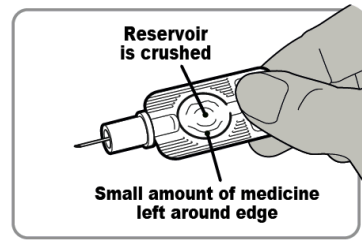


Step 8: Inject the dose

- Gently pinch a large area of skin with one hand. Keep the skin pinched all through this step.
- With the other hand, hold the injector by the port with the needle pointing downwards.
- Insert the needle into the skin until the port just touches the skin.
- Squeeze the reservoir **slowly** to inject the medicine. You should take about **5-7 seconds** to do this.
- Gently pull the needle out of the skin. Let go of the skin.
- Check whether the medicine has leaked out of the injector or has appeared on the skin. If so, a problem has occurred. (Please refer to information overleaf).

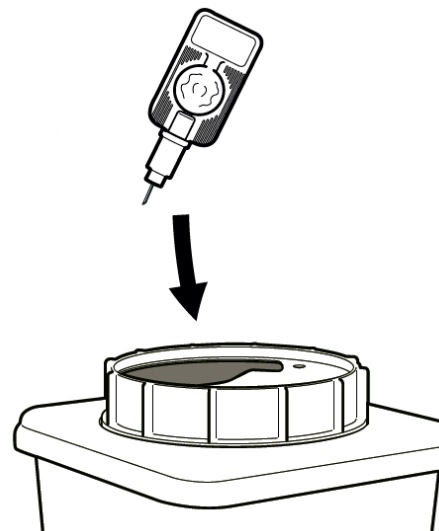


- After the injection, a small amount of medicine will be left around the inside edge of the reservoir. This is normal.
- If you believe for any reason that the full dose has not been given, speak to your Healthcare provider about alternative methods of contraception until the next scheduled injection.
- **Do not** inject a second dose.
- Use a clean cotton pad to press lightly on the injection area for a few seconds
 - **Do not** rub the area.



Step 9: Dispose the injector

- Immediately dispose of the used injector into a suitable sharps container.
- Do not put the needle shield back on the needle to avoid injuring yourself.
- The injector is for a single injection only.
 - **Do not** reuse the injector.



After injection care

- Monitor the appearance of the injection site until the next injection.

If you notice any skin indentation or dimpling at the injection site tell your Healthcare provider.
- If you experience any symptoms of allergic reaction (see section **9.0 Undesirable effects of this medicine**), seek medical help immediately.

<p>Record the date</p> <p>Record the date of your injection and should you wish to continue, calculate the date of your next scheduled injection of SAYANA PRESS.</p>	<p>Date</p> <p>_____</p> <p>Date of next injection (add 3 months)</p> <p>_____</p>
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Administration of Medroxyprogesterone acetate (Sayana Press) 104 mg/0.65 mL pre-filled single dose injector should be initiated under the supervision of a healthcare professional (HCP). After proper training in injection technique and schedule of administration, patients may self-inject with Medroxyprogesterone acetate (Sayana Press) 104 mg/0.65 mL pre-filled single dose injector if their HCP determines that it is appropriate and with medical follow-up as necessary.

Initial injection

The initial SC injection should be given during the first 5 days after the onset of a normal menstrual period; within 5 days postpartum if not breast feeding; or, if exclusively breast-feeding, at or after 6 weeks postpartum.

Second and subsequent injections

If more than 14 weeks have elapsed since the last SC injection, pregnancy should be ruled out before administering the next SC injection.

Switching from other methods of contraception

When switching from other contraceptive methods, Medroxyprogesterone acetate (Sayana Press) should be given in a manner that ensures continuous contraceptive coverage based upon the mechanism of action of both methods, (e.g., patients switching from oral contraceptives should have their first injection of Medroxyprogesterone acetate (Sayana Press) within 7 days after taking their last active pill).

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

Gynecology

Use of combined estrogen / progestin therapy in postmenopausal women should be limited to the lowest effective dose and the shortest duration consistent with treatment goals and risks for the individual woman, and should be periodically evaluated. Periodic check-ups are recommended with a frequency and nature adapted to the individual woman. Unless there is a previous diagnosis of endometriosis, it is not recommended to add a progestin in a woman without an intact uterus.

Endometriosis

Injectable Medroxyprogesterone acetate (Sayana Press) given subcutaneously 104 mg every 3 months for at least 6 months.

7.0 WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

Do not take medroxyprogesterone acetate (Sayana Press)

- If you are allergic (hypersensitive) to medroxyprogesterone acetate or any of the other ingredients of medroxyprogesterone acetate (Sayana Press), or any component of the drug such as Methyl Parahydroxybenzoate, Propyl Parahydroxybenzoate, Sodium Chloride, Polyethylene Glycol, Polysorbate 80, Monobasic Sodium Phosphate, Disodium Phosphate Dodecahydrate, Methionine, Povidone, Sodium Hydroxide and Hydrochloric acid;
- If you are pregnant or suspect you may be pregnant;
- If you have vaginal bleeding of unknown cause;
- If you have problems with your liver or liver disease;

- If you have or suspect breast cancer

MPA has not been causally associated with the appearance of thrombotic or thromboembolic disorders, however MPA is not recommended in any patient with a history of venous thromboembolism (VTE). MPA should be discontinued in patients who develop VTE while undergoing therapy with MPA.

8.0 CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

Talk to your doctor or healthcare professional before using medroxyprogesterone acetate (Sayana Press).

Medroxyprogesterone acetate (Sayana Press) is a very effective injectable contraceptive which gives 14 weeks' continuous contraception with each injection. The effect is not reversible once the injection is given. Medroxyprogesterone acetate (Sayana Press) may not be suitable for every woman. You will need to discuss with your doctor or healthcare professional providing your contraception whether it is suitable for you, especially if you wish to use it for more than 2 years.

Before your doctor or healthcare professional prescribes medroxyprogesterone acetate (Sayana Press), you may need to have a physical examination. This examination will be repeated every year. It is important to tell your doctor or healthcare professional if you have, or have had in the past, any of the following conditions. Your doctor will then discuss with you whether medroxyprogesterone acetate (Sayana Press) is suitable for you

- if you have or have had a condition likely to be negatively influenced by weight gain or water retention;
- if you have past history of or current depression;
- if you have diabetes or a family history of diabetes;
- if you have blood clotting disorders, such as thrombotic or thromboembolic disorders such as venous thromboembolism (VTE);
- if you experience any change in the menstrual bleeding patterns (e.g., irregular or unpredictable bleeding/spotting, rarely, heavy or continuous bleeding);
- if you develop jaundice (liver problems), do not readminister the drug;
- if you experience a long effect of contraception (not able to conceive for a long time).
- if there is a sudden partial or complete loss of vision or another problem pertaining to the eye.

The physician/laboratory should be informed that use of MPA may decrease the levels of the following endocrine biomarkers:

- Plasma/urinary steroids (e.g., cortisol, estrogen, pregnanediol, progesterone, testosterone)
- Plasma/urinary gonadotropins (e.g., LH and FSH)
- Sex-hormone-binding-globulin

Please inform your doctor if you need to have any blood tests or gynecological assessment, as medroxyprogesterone acetate (Sayana Press) may affect their results.

MPA has not been causally associated with the appearance of thrombotic or thromboembolic disorders, however MPA is not recommended in any patient with a history of venous thromboembolism (VTE). MPA should be discontinued in patients who develop VTE while undergoing therapy with MPA.

Liver Insufficiency

No clinical studies have evaluated the effect of liver disease on the effect of MPA. However, MPA is almost exclusively eliminated by metabolism in liver and steroid hormones may be poorly metabolized in patients with severe liver insufficiency (see section **7.0 When you should not take this medicine?**).

Kidney Insufficiency

No clinical studies have evaluated the effect of kidney disease on the effect of MPA. However, since MPA is almost exclusively eliminated by metabolism in liver, no dosage adjustment should be necessary in women with kidney insufficiency.

Pregnancy and lactation

Your doctor will check that you are not pregnant before giving you the first injection and also if any following injection is delayed beyond 14 weeks.

Because medroxyprogesterone acetate (Sayana Press) is such an effective contraceptive method, the risk of accidental pregnancy for women who have their injections regularly (every 14 weeks) is very low. Medroxyprogesterone acetate (Sayana Press) must not be taken if you are pregnant as hormonal medicines can affect the developing baby. Infants from unintentional pregnancies that occur 1 to 2 months after injection of MPA injectable suspension may be at an increased risk of low birth weight, which, in turn, is associated with an increased risk of neonatal death. The attributable risk is low because pregnancies while on Medroxyprogesterone acetate (Sayana Press) are uncommon. Several reports suggest an association between mothers who take these drugs in the first trimester of pregnancy and genital abnormalities in male and female babies.

If you think you may have become pregnant while using medroxyprogesterone acetate (Sayana Press) for contraception, tell your doctor immediately.

Medroxyprogesterone acetate (Sayana Press) passes into breast milk. There is no indication that it causes risks to breastfed newborns. Ask your doctor or pharmacist before taking any medicine.

Driving and using machines

No effect on the ability to drive or use machines has been established.

9.0 UNDESIRABLE EFFECTS OF THIS MEDICINE

Like all medicines, medroxyprogesterone acetate (Sayana Press) can cause side effects although not everybody gets them.

Other side effects include:

- Inflammation of vagina resulting in whitish or yellowish vaginal discharge, itching and pain;
- Allergic reaction, swelling on face, tongue, larynx, abdomen, or arms and legs, allergic reaction due to drug;
- Weight change (increase or decrease), changes in appetite;
- Mood changes, including depression and anxiety, insomnia, emotional disorder, changes in sex drive; sleeplessness;
- Dizziness, sleepiness, tiredness, headache, migraine, sudden spinning sensation, tingling or prickling, “pins-and-needles” sensation;
- Palpitations, hypertension, enlarged veins;
- Nausea, abdominal pain/discomfort, abdominal distension;
- Acne, male-pattern hair growth in women (hirsutism), hair loss, hives, rash, dermatitis, discoloration of the skin resulting from bleeding underneath, dark, discolored patches on skin, lipodystrophy acquired (characterized by fat loss affecting large areas of the body, particularly the face, arms, and legs);
- Back pain, muscle pain, multiple joint pain, pain in limbs;
- Painful periods, missed periods, changes in bleeding patterns, vaginal discharge, vulvovaginal dryness, ovarian cyst, premenstrual syndrome, uterine hemorrhage, vaginal hemorrhage, breast pain, tenderness, milk secretion, pelvic pain;
- Decrease in glucose tolerance, abnormal liver enzymes and cervical smear result;
- Decrease in bone density (thinning of bones);

- Injection site reactions (such as pain/tenderness, nodule/lump, persistent atrophy/indentation/dimpling, lipodystrophy, injection site discoloration), fatigue, irritability;

Possible effect on your periods

Medroxyprogesterone acetate (Sayana Press) will usually disturb the pattern of a woman's period.

After the first injection it is most likely that you will have irregular, possibly lengthy bleeding or spotting. This will continue in some women. This is quite normal and nothing to worry about.

If you experience very heavy or prolonged bleeding you should talk to your doctor. This happens rarely but can be treated.

When you stop taking medroxyprogesterone acetate (Sayana Press) your periods will return to normal in a few months.

Weight Gain: There is a tendency for women to gain weight while on medroxyprogesterone acetate (Sayana Press) therapy.

Protection against Sexually Transmitted Diseases: Medroxyprogesterone acetate (Sayana Press) does not protect against HIV infection (AIDS) and other sexually transmitted diseases. However, if used as directed, you will not be exposed to sexually transmitted infections. Women should practice safe sex including correct and consistent use of condoms to prevent STIs.

Possible effects on your bones

The following are risk factors in the development of osteoporosis in later life. You should discuss with your doctor before starting treatment if you have any of the following as an alternative contraceptive may be more suitable to your needs:

- Chronic alcohol and/or tobacco use;
- Chronic use of drugs that can reduce bone mass, e.g. epilepsy medication or steroids;
- Low body mass index or eating disorder, e.g., anorexia nervosa or bulimia;
- Metabolic bone disease;
- Strong family history of osteoporosis.

It is recommended that all patients have adequate calcium and Vitamin D intake.

Possible risk of breast cancer

Medroxyprogesterone acetate (Sayana Press) may increase the risk of breast cancer slightly compared with women who have never used it. However, any excess risk is small in relation to the overall risk of breast cancer, particularly in young women.

The potential for an increased risk of coronary disease should be considered prior to use.

10.0 WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

Always tell your doctor or healthcare professional who treats you that you are using medroxyprogesterone acetate (Sayana Press) as a contraceptive if you are taking or have recently taken any other medicines, even those you bought yourself without a prescription, because medicines can sometimes interact with each other.

Tell your doctor or healthcare professional if you are taking a medicine called aminoglutethimide (used in Cushing's syndrome) as these may affect the way medroxyprogesterone acetate (Sayana Press) works.

The results of a cervical smear and some laboratory tests could also be affected if you are using medroxyprogesterone acetate (Sayana Press) so it is important that you tell your doctor.

11.0 WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss your injection or are late in getting your next injection (i.e., wait longer than 14 weeks between injections), there is a greater risk that you could become pregnant. Ask your doctor or healthcare professional to find out when you should receive your next injection of medroxyprogesterone acetate (Sayana Press) and which type of additional contraception should be used in the meantime.

12.0 SIGNS AND SYMPTOMS OF OVERDOSE

Overdose treatment is symptomatic and supportive.

13.0 WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

Further treatment of overdose, if necessary, is directed to the symptoms. If you have used or taken too much medroxyprogesterone acetate (Sayana Press), in all cases, immediately contact your doctor, pharmacist or Poison Control Center.

14.0 HOW SHOULD YOU KEEP THIS MEDICINE?

- Keep out of the reach of children.
- Store at temperatures not exceeding 30°C. Do not refrigerate or freeze.

15.0 WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Tell your doctor immediately if you notice any of the following:

- In case of unexpected vaginal bleeding. Most women who use medroxyprogesterone acetate (Sayana Press) have disturbed menstrual bleeding patterns, which may include irregular or unpredictable bleeding, or "spotting", or rarely heavy or continuous bleeding. With continued treatment, patients are less likely to suffer from irregular bleeding and more likely to have missed periods.
- Problems with your eyesight while using medroxyprogesterone acetate (Sayana Press); for example, a sudden partial or complete loss of vision or double vision.

16.0 FDA REGISTRATION NUMBER

104 mg/ 0.65 mL Suspension for Subcutaneous (SC) Injection: DR-XY47081.

17.0 DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

104 mg/ 0.65 mL Suspension for Subcutaneous (SC) Injection: 14 January 2021.

Keep out of reach of children.

For suspected adverse drug reaction, report to the FDA: www.fda.gov/ph

Seek medical attention immediately at the first sign of any adverse drug reaction.

CAUTION: Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Manufactured By:

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Marketing Authorization Holder:

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Philippines

Revision No.: PIL revision number 2.1
Revision Date: 07 November 2024
Reference: Medroxyprogesterone Acetate
(Sayana Press) LPD version No. 2.1
Reference date: 07 November 2024