

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

SAYANA® 104 mg/0,65 mL suspension for injection

Pre-filled injection

Medroxyprogesterone acetate

Sugar free

Read all of this leaflet carefully before you start using SAYANA

- 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.
- SAYANA 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 SAYANA is and what it is used for
2. What you need to know before you use SAYANA
3. How to use SAYANA
4. Possible side effects
5. How to store SAYANA
6. Contents of the pack and other information

1. What SAYANA is and what it is used for

- For contraception where you and the person who provides your contraception (e.g., your doctor, nurse or health care provider) have decided that this method is the most suitable for you. However, if you wish to use SAYANA for more than 2 years, your health care provider/doctor/nurse may wish to re-evaluate the risks and benefits of using SAYANA to make sure that it is still the best option for you.
- To treat endometriosis-associated pain.

The active ingredient in SAYANA, medroxyprogesterone acetate, 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. SAYANA 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 fertilised by sperm and result in pregnancy.

2. What you need to know before you use SAYANA

Do not use SAYANA:

- if you are hypersensitive (allergic) to medroxyprogesterone acetate or any of the other ingredients of SAYANA (listed in section 6)
- if you think you are pregnant, are pregnant or breastfeeding your baby
- if you have unexplained vaginal bleeding
- if you have severe liver disease
- if you have had or think you have cancer of the breast
- if you have inflammation in the wall of a vein often occurring in the legs
- if you have meningioma or have ever been diagnosed with a meningioma (a usually benign tumour of the tissue layer surrounding the brain and spinal cord).

Warnings and precautions

Before your doctor prescribes SAYANA, you should undergo a complete medical examination that includes blood pressure, breasts, abdomen and pelvic organs and a pap smear.

It is important to tell your doctor if you have, or have had in the past, any of the following conditions/habits. Your doctor will then discuss with you whether SAYANA is suitable for you.

Take special care with SAYANA:

- if you have risk factors for osteoporosis (brittle bones) including
 - chronic alcohol and/or tobacco use
 - chronic use of drugs that can reduce bone mass, e.g., anticonvulsants or corticosteroids
 - low body mass index (BMI) or eating disorder, e.g., anorexia nervosa or bulimia
 - metabolic bone disease
 - strong family history of osteoporosis
- if you have a history of abnormal or unexpected vaginal bleeding (e.g., irregular, light or heavy periods) as you may need additional examination or testing before using SAYANA
- 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 SAYANA
- 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 SAYANA
- if you have a condition that may be affected by weight gain or fluid retention as SAYANA may cause these conditions to worsen (e.g., epilepsy, migraine, asthma, or problems with your heart or kidneys)
- if you have a past history of depression
- 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 SAYANA may cause higher than normal blood glucose (sugar) levels

Hormonal contraceptives, including SAYANA, 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 SAYANA may cause a decrease in the amount of calcium and other minerals in your bones. This can increase risk of developing osteoporosis which can lead to bone breakages in later life. Your health care provider will assess this risk before prescribing SAYANA and if you continue using SAYANA for more than 2 years. Bones start to recover when SAYANA is stopped. It is recommended that you have adequate calcium and vitamin D intake while using SAYANA.

It is important to be aware that your menstrual cycle may be disrupted during treatment with SAYANA. At the beginning of your treatment, SAYANA may cause irregular bleeding and spotting. This usually decreases until complete absence of any bleeding, as such, the onset of 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 SAYANA. It is important to tell the health care provider you are using SAYANA if any medical tests and/or samples are being taken.

If you develop yellowing of the skin or eyes (jaundice), you should consult your health care provider before receiving additional injections of SAYANA.

Meningioma

Use of SAYANA has been linked to the development of a usually benign tumour of the tissue surrounding the brain and spinal cord (meningioma). The risk increases especially when you use it for longer duration (several years). If you are diagnosed with meningioma, your doctor will stop your treatment with SAYANA (see section 'Do not take SAYANA'). If you notice any symptoms such as changes in vision (e.g. seeing double or blurriness), hearing loss or ringing in the ears, loss of smell, headaches that worsen with time, memory loss, seizures, weakness in your arms or legs, you must tell your doctor straightaway.

Protection against sexually transmitted diseases

SAYANA does not protect against sexually transmitted infections (STIs) including HIV infection (AIDS). Using SAYANA 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.

Children and adolescents

When used in teenagers (12 – 18 years of age), SAYANA may cause bones to become thinner at a time when they should be growing and increasing in strength. In this age group, bones start to recover when SAYANA is stopped.

Other medicines and SAYANA

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

There are some medicines that may interact with SAYANA and cause undesirable effects.

Medicines can sometimes interfere with each other. If you receive treatment from any other doctor, nurse or qualified health care provider make sure they are aware that you are using SAYANA.

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 SAYANA 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.

Do not take SAYANA if you are pregnant. If you think you may have become pregnant while using SAYANA, tell your doctor immediately.

You should not breastfeed your baby while taking SAYANA. Please discuss this with your health care provider, as SAYANA can be passed to the nursing infant in the breast milk.

Driving and using machines

It is not always possible to predict to what extent SAYANA 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 SAYANA affects them.

Dizziness is a potential side effect. Patients should be aware of how they might be affected by SAYANA before driving or operating machinery.

SAYANA contains methyl parahydroxybenzoate and propyl parahydroxybenzoate

SAYANA contains the following two ingredients: methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216). These ingredients may cause allergic reactions (possibly delayed), and exceptionally bronchospasm.

SAYANA contains less than 1 mmol sodium (23 mg) per 104 mg/0,65 mL, i.e., essentially 'sodium-free'.

3. How to use SAYANA

When you start using SAYANA, the medicine should be administered by your doctor, nurse or health care provider. If you are using SAYANA for contraception, you may be able to self-inject your medicine following suitable instruction and training on injection technique and schedule of administration, if considered appropriate by your health care provider.

Method and route of administration

SAYANA is injected under the skin into the front upper thigh or abdomen.

Further injections

Further doses of SAYANA will then be given every 12 to 14 weeks (but no later than 14 weeks past your last injection). It is important that your next injections are given at the right time.

If you are giving yourself injections, ensure you have a way of reminding yourself (for example a calendar, diary or phone alert) so you know when to give yourself the next injection.

Your doctor will tell you how long your treatment with SAYANA will last. If you have the impression that the effect of SAYANA is too strong or too weak, tell your doctor or pharmacist.

Self-injection

The first injection of SAYANA will be administered under the supervision of your doctor, nurse or health care provider. If your doctor considers it appropriate, you may choose to give yourself the next injections. You will be shown how to give yourself the injection under supervision before you do this on your own at home. The detailed instructions on the injection procedure below should be followed very carefully.

Instructions for use

Preparing and giving an injection with SAYANA Pre-filled injection

When used for contraception, SAYANA Pre-filled injection can be given by a health care provider or the patient.

Introduction

SAYANA Pre-filled injection 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.

SAYANA Pre-filled injection should be at room temperature. It must be vigorously shaken just before use to ensure that the dose being given represents a uniform suspension. The contents are completely sealed inside the reservoir of the injector. The injector must be activated before use. The activation process pierces an internal seal so that the medicine can come out through the needle when the reservoir is squeezed. The liquid does not completely fill the reservoir. There is a small bubble of air above the liquid. The dose is administered as a subcutaneous injection (SC) into the anterior thigh or abdomen. When the injection is being given, the injector must be used with the needle downwards. This ensures that the full dose of liquid is delivered out through the needle. The medicine should be injected slowly for 5 - 7 seconds.

Important points to note

Choose an injection site (abdomen or front upper thigh) that you find easy to see and reach with both hands and find a sitting position which is comfortable for you. Try to use a different injection site for each injection so you are not injecting into the same place too often.

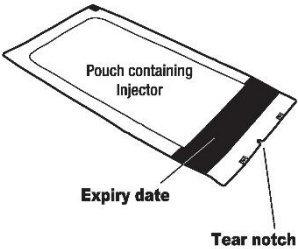
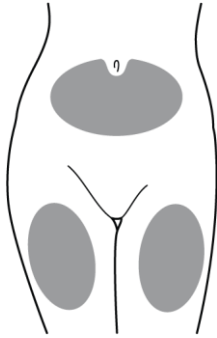
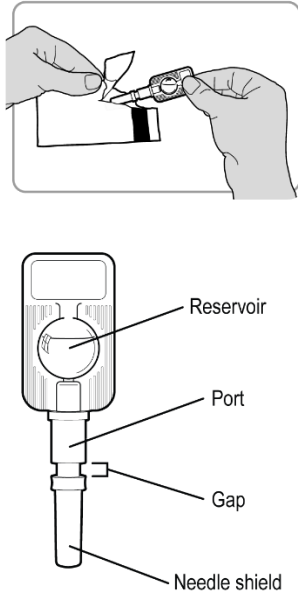
When giving yourself the injection, you must squeeze the injector with slow even pressure over 5 - 7 seconds to push out the medicine. If you try to squeeze too quickly you may feel resistance and be unable to inject the medicine. If this happens, adjust your grip if necessary and squeeze more gently to fully push out the medicine.

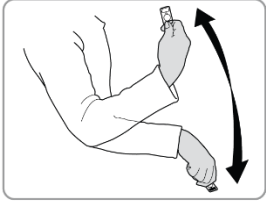
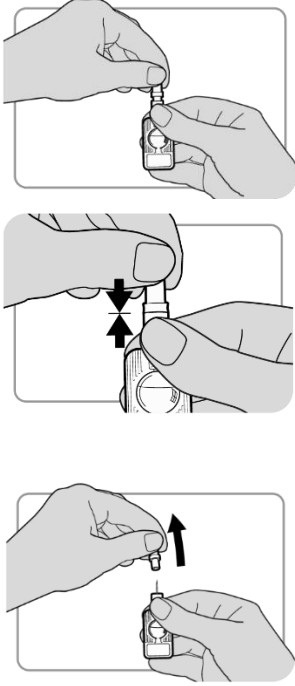
It is normal for a very small amount of medicine to be left around the edges of the blister (reservoir). If you have had a problem during the injection or if you feel for any reason, you might not have given yourself the full dose, do NOT give yourself an additional injection. It is important you get advice from your doctor, nurse or health care provider because a partial dose may not prevent pregnancy.

If, at any time, you don't want to continue injecting yourself for any reason, speak to your doctor, nurse or health care provider before your next injection is due, so they can arrange to give it to you at the right time.

It is recommended that you continue to see your doctor or health care provider periodically as recommended by your health care provider, at least once a year as a minimum, so they can check SAYANA is still the best option for you and for you to have routine contraceptive health checks.

If you have any questions or worries ask your doctor, nurse, or health care provider for advice, particularly if there have been any problems during or immediately after the injection.

Step 1. Getting ready You will need – A SAYANA injector (in its sealed foil pouch). – A suitable container for the used injector. – A clean cotton pad or clean paper tissue. • Wash and dry your hands thoroughly before starting. • Check that the pouch does not appear to be damaged. • Check that the expiry date has not passed. • Ensure the pouch is at room temperature.	
Step 2. Selecting an injection area • Choose a suitable area for the injection, either the abdomen or the front upper thigh. Avoid bony areas and the navel (belly button). • The area of skin must be free from scars and skin conditions such as eczema or psoriasis. • Change the site with each injection • Clean the area of skin as your health care provider has told you.	
Step 3. Preparing the injector • Carefully tear open the foil pouch at the tear notch. • Take out the injector. Do not remove the needle shield from the injector yet. • Check the injector. There should be a gap between the needle shield and the port. • Discard the injector and use a new one if: – There is no gap. – The injector is damaged. • The needle shield has come off or is missing.	

Step 4. Mixing the medicine • Hold the injector firmly by the port. • Shake the injector vigorously for at least 30 seconds to mix the medicine. •	
Step 5. Activating the injector • Hold the injector firmly by the port, making sure the needle shield is pointing upwards. Take care not to squeeze the reservoir. • Hold the needle shield with the other hand. • Push the needle shield firmly towards the port until it will go no further. The injector is now activated. • Pull the needle shield off and discard it.	

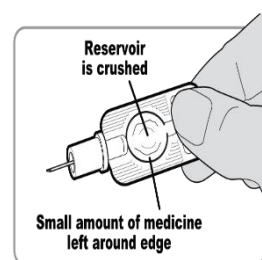
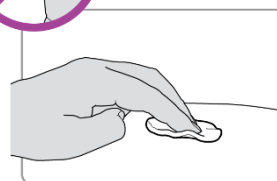
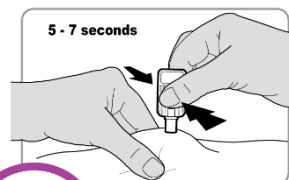
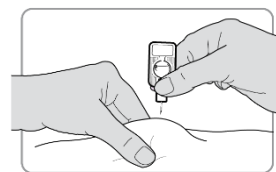
Step 6. Injecting the dose

- Gently pinch a large area of skin. Keep the skin pinched all through this step.
- Hold the injector by the port with the needle pointing straight downwards.
- Insert the needle into the skin so that 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 any medicine has leaked out of the injector or has appeared on the skin.
- **Do not replace the needle shield.**
- Use a clean cotton pad to press lightly on the injection area for a few seconds. Do not rub the area.

Important advice

- After the injection a small amount of medicine will be left around the inside edge of the reservoir. This is normal.
- However, if any medicine has leaked out of the injector or appeared on the skin, then a problem may have occurred.
- **If you believe for any reason that the full dose has not been given, speak to your health care provider about alternative methods of contraception until the next scheduled injection.**
- **Do not inject an additional dose.**

After injection care:



• If you get any symptoms of allergic reaction (see section 4) seek medical help immediately. • 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 health care provider.	
Step 7. Disposing of the injector • Immediately dispose of the used injector into a suitable container in accordance with your local authority requirements or as you have been told by your health care provider. • The injector is for a single injection only and must not be re-used	
Step 8. Record the date of your injection and should you wish to continue, calculate the date of your next scheduled injection of SAYANA. Retain this leaflet for your records.	Date _____ Date of Next Injection (add 3 months) _____

If you use or receive more SAYANA than you should

When a health care provider administers SAYANA, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage. Your doctor, nurse or health care provider will take the necessary corrective actions.

If you are using SAYANA for contraception, you may be able to self-inject your medicine if considered appropriate by your health care provider. In the event of overdosage with self-injection, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use SAYANA

If you miss your injection or wait longer than 14 weeks between injections, there is a greater risk that you could become pregnant if using SAYANA for contraception. Do not use or receive a double dose to make up for forgotten individual doses. Ask your doctor, pharmacist, or health care provider when your next injection of SAYANA should be administered. If using SAYANA for contraception, ask your health care provider which type of contraception should be used in the meantime.

Switching from other methods of contraception

When you switch from other contraceptive methods, your doctor will make sure you are not at risk of becoming pregnant by giving you your first injection at the appropriate time. If you switch from oral contraceptives, you should have your first injection of SAYANA within 7 days after taking your last active pill.

What if you decide you want to get pregnant

Your usual level of fertility will return when the effect of the last injection has worn off. The time this takes varies in different women and does not depend on how long you have been using SAYANA. In most women the effect will have worn off 5 to 6 months after the last injection. It is possible to get pregnant in the first month after missing an injection.

4. Possible side effects

SAYANA can have side effects.

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

If any of the following happens, stop using SAYANA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty swallowing or breathing
- signs of an allergic reaction including rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to SAYANA. 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

- increased weight
- depression
- decrease in libido
- mood disorder
- anxiety
- difficulty sleeping
- irritability
- headache
- dizziness
- migraine
- abdominal pain
- nausea (feeling sick)
- acne
- skin irritation
- back pain
- pain in limbs

- very light or no menstrual bleeding (period)
- breast pain
- changes to menstrual bleeding patterns (e.g., abnormally heavy, unexpected, prolonged, painful)
- vaginal inflammation (e.g., irritation or itching)
- fatigue
- injection site reaction
- abnormal cervical smear (Pap smear)

Less frequent side effects

- decreased weight
- increased or decreased appetite
- fluid retention
- inability to reach orgasm
- emotional disorders
- vertigo (imbalance)
- hot flushes
- high blood pressure
- varicose veins
- bloating
- excessive hair growth
- patchy brown skin discolouration on the face
- bruising
- rash
- hair loss
- muscle spasms
- breast tenderness
- vaginal discharge
- vaginal dryness

- change in breast size
- pain during sexual intercourse
- ovarian cyst
- pelvic pain
- premenstrual syndrome
- abnormal liver enzymes

Frequency not known

- fat loss from a specific area, becoming extremely thin
- injection site reactions such as pain/tenderness, nodule/lump, persistent indentation/dimpling, discolouration
- usually benign tumour of the tissue surrounding the brain and spinal cord (meningioma) (see section 2 "Warnings and precautions").

When used for endometriosis

Frequent side effects

- increased weight
- anxiety
- depression
- difficulty sleeping
- irritability
- decrease in libido
- mood disorder
- headache
- dizziness
- feeling of having insects crawling on or under the skin
- excessive sleepiness

- migraine
- hot flushes
- nausea (feeling sick)
- bloating
- acne
- hair loss
- skin irritation
- joint pain
- pain in limbs
- changes to menstrual bleeding patterns (e.g., abnormally heavy, unexpected, prolonged, painful)
- breast pain
- breast tenderness
- vaginal inflammation (e.g., irritation or itching)
- pelvic pain
- vaginal dryness
- fatigue

Less frequent side effects

- tingling sensation (pins and needles)
- palpitations
- pain in multiple joints
- production of breast milk not associated with childbirth or nursing
- ovarian cyst

Frequency not known

- decreased weight
- fat loss from a specific area, becoming extremely thin

- injection site reactions such as pain/tenderness, nodule/lump, persistent indentation/dimpling, discolouration
- usually benign tumour of the tissue surrounding the brain and spinal cord (meningioma) (see section 2 'Warnings and precautions').

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SAYANA.

You can report any suspected adverse drug reactions associated with the use of the medicine directly to Pfizer via ZAF.AEReporting@pfizer.com.

5. How to store SAYANA

- Store all medicines out of reach of children.
- Store at or below 25 °C and protect from light.
- Do not refrigerate or freeze.
- Do not use SAYANA after the expiry date stated on the injection system, foil pouch and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Once opened: use immediately, discard any unused portion.

6. Contents of the pack and other information

What SAYANA contains

- The active substance is medroxyprogesterone acetate 104 mg/0,65 mL.

- The other ingredients are methyl parahydroxybenzoate (1,04 mg/0,65 mL), propyl parahydroxybenzoate (0,0975 mg/0,65 mL), sodium chloride, macrogol (polyethylene glycol) 3350, polysorbate 80, monobasic sodium phosphate · 1 H₂O, disodium phosphate dodecahydrate, methionine, povidone, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and water for injection.

What SAYANA looks like and contents of the pack

White to off white homogenous suspension

SAYANA Pre-filled injection: A single 1 mL pre-filled multi-layered thermoformed plastic film reservoir, affixed with a single-use 23-gauge needle, is packed in a foil laminate pouch (single pack) or in a box containing 200 single pre-filled clear plastic reservoirs with needles in a foil pouch.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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