

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

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

Pre-filled syringe

Medroxyprogesterone acetate

Sugar free

Read all of this leaflet carefully before you are given 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 are given 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 are given SAYANA

SAYANA should not be administered to you:

- 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

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.

Tell your doctor or health care provider before being given the injection if you have:

- 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 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 giving you 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.

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

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

SAYANA should be administered by your doctor, nurse or 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 you receive your next injections at the right time.**

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.

If you are given more SAYANA than you should

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

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 receive a double dose to make up for forgotten individual doses. Ask your doctor, pharmacist, or health care provider ~~to find out~~ when you should receive your next injection of SAYANA. ~~and~~ 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 ~~breathing in,~~ 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

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

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 SAYANA.

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.
- 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 syringe: A single 2,25 mL glass syringe with fluoro-coated bromobutyl rubber plunger stopper and bromobutyl rubber tip cap is assembled with the plunger rod. The assembled syringe is placed in a tray and the needle is added to the package. The tray is sealed with a foil. Tray and printed materials are

packaged in a carton. Single pack for single use only.

Holder of Certificate of Registration

Pfizer Laboratories (Pty) Ltd

85 Bute Lane

Sandton 2196

South Africa

Tel: +27(0)11 320 6000 / 0860 734 937 (Toll-free South Africa)

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