

Package leaflet: Information for the user

SAYANA PRESS[®] 104 mg/0.65 ml suspension for injection
Single-dose container
Medroxyprogesterone acetate

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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What SAYANA PRESS is and what it is used for

SAYANA PRESS is a contraceptive. It can be used:

- For long-term contraception where you and the person who provides your contraception (e.g. your doctor, nurse or healthcare provider) have decided that this method is the most suitable for you. However, if you wish to use SAYANA PRESS for more than 2 years, your health professional/doctor/nurse may wish to reevaluate the risks and benefits of using SAYANA PRESS to make sure that it is still the best option for you.
- By teenagers, but only after other methods of contraception have been discussed with the person who provides your contraception and are considered unsuitable or unacceptable.

The active ingredient in SAYANA PRESS, medroxyprogesterone acetate (MPA), 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 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 fertilised by sperm and result in pregnancy.

2. What you need to know before you use SAYANA PRESS

Do not use SAYANA PRESS:

- If you are allergic (hypersensitive) to medroxyprogesterone acetate (MPA) or any of the other ingredients of SAYANA PRESS (listed in section 6)
- If you think you may be pregnant
- If you have unexplained vaginal bleeding
- If you have liver disease
- If you have had or think you have cancer of the breast or sex organs
- If you have a blood clot in a vein in your leg (a 'deep vein thrombosis') or a blood clot that has travelled to your lung or another part of your body (an 'embolus')

- If you have problems with your circulation (e.g. pains in your legs or chest when you walk), or with your blood clotting too easily ('thrombosis' or 'embolism')
- If you have been diagnosed with thinning, softening or weakening of your bones
- If you have or have had a disease affecting the blood vessels of the brain

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using SAYANA PRESS

Before your doctor prescribes SAYANA PRESS, you may need to have a physical examination.

It is important to tell your doctor if you have, or have had in the past, any of the following conditions.

Your doctor will then discuss with you whether SAYANA PRESS is suitable for you.

Tell your doctor if you have:

- Migraine headaches
- Diabetes or a family history of diabetes
- Severe pain or swelling in the calf (indicating a possible clot in the leg, which may be called phlebitis)
- A blood clot in the lung (pulmonary embolism)
- A blood clot in your eye affecting your vision (retinal thrombosis)
- A history of heart disease or cholesterol problems including any family history
- Past history of depression
- Irregular, light, or heavy menstrual periods
- An unusual breast x-ray, fibrocystic breast disease, breast nodules or lumps, or bleeding from your nipples
- Had a stroke
- Family history of breast cancer
- Kidney disease
- High blood pressure
- Asthma
- Epilepsy.

Protection against sexually transmitted diseases

SAYANA PRESS does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

Other medicines and SAYANA PRESS

Please tell your doctor, pharmacist or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. There are some medicines that may interact with SAYANA PRESS. These include medicines that thin your blood (anticoagulants).

Medicines can sometimes interfere with each other. If you receive treatment from any other doctor, nurse or qualified healthcare professional make sure they are aware that you are using SAYANA PRESS as a contraceptive.

Pregnancy and breast-feeding

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

If you are breast-feeding, the injection should be given no sooner than 6 weeks after childbirth, when the baby is more developed. SAYANA PRESS can be passed to the nursing infant in the breast milk, however no harmful effects have been found in children.

Always ask your doctor, nurse, or healthcare professional for advice before taking any medicine.

Driving and using machines

No effects on the ability to drive or use machines have been seen with SAYANA PRESS.

SAYANA PRESS contains methyl parahydroxybenzoate (E218) & propyl parahydroxybenzoate (E216) and sodium

Methyl parahydroxybenzoate (E218) & propyl parahydroxybenzoate (E216). These may cause allergic reactions (possibly delayed).

This medicinal product contains less than 1 mmol sodium (23 mg) per 104 mg/0.65 ml, i.e. essentially 'sodium-free'.

3. How to use SAYANA PRESS

Administration of SAYANA PRESS is initiated by a healthcare professional (HCP). If considered appropriate by the HCP, you may be able to self-inject your injections following suitable instruction and training on injection technique and schedule of administration.

Method and route of administration

SAYANA PRESS is injected under the skin into the front upper thigh or abdomen. The first injection should be performed under the supervision of your doctor, nurse, or healthcare provider. If your doctor considers it appropriate you may choose to give yourself the 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 are provided at the end of this leaflet and should be followed very carefully. You should continue to receive SAYANA PRESS for as long as instructed by your doctor or until you want to have a baby or switch to a different method of contraception.

First injection

A dose of 104 mg of SAYANA PRESS is given subcutaneously (into the fatty layer just under the skin), into the front upper thigh or abdomen every 3 months (12 to 13 weeks). SAYANA PRESS will only be effective if you receive your injection at the proper time. To ensure that you are not pregnant at the time of the first injection, it is essential that your first injection be given **ONLY** during the first 5 days of your normal menstrual cycle.

After childbirth: If you use SAYANA PRESS after having a baby and you are not breastfeeding, the first injection **MUST** be given within 5 days.

There is evidence that women prescribed SAYANA PRESS immediately after childbirth or termination of pregnancy can experience prolonged and heavy bleeding. Because of this, SAYANA PRESS should be used with caution at this time.

Further injections

Further doses of SAYANA PRESS will then be given every 12 to 13 weeks, (but no later than 14 weeks past your last injection), regardless of when and how much menstrual bleeding you have.

It is important that you have your next injections at the right time.

Planning your injections

- 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.

Preparing for an injection

1. 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.

2. Make sure the medicine is at room temperature. Carefully tear open the foil pouch at the tear notch and take out the injector.
3. Hold the injector firmly and shake it vigorously for at least 30 seconds to mix the medicine.

Giving yourself injections:

Carefully follow the **step by step instructions** at the end of this leaflet on how to give yourself the injection.

Important points to note:

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 healthcare 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 healthcare 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 healthcare provider periodically as recommended by your HCP at least once a year as a minimum so they can check SAYANA PRESS 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 healthcare professional for advice, particularly if there have been any problems during or immediately after the injection.

If you miss an injection of SAYANA PRESS

If you miss your injection or wait longer than 14 weeks between injections, there is a greater risk that you could become pregnant. Tell your doctor, pharmacist, or healthcare professional to find out when you should have your next injection of SAYANA PRESS and 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 PRESS within 7 days after taking your last 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 PRESS. In most women the effect will have worn off 5 to 6 months after the last injection. Over 80 % of women will get pregnant within a year of stopping SAYANA PRESS. It is possible to get pregnant in the first month after missing an injection.

4. Possible side effects

Like all medicines, SAYANA PRESS can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you are injecting SAYANA PRESS yourself and not seeing your doctor as regularly, it is important you are aware of possible side effects, how to recognise them and when to get urgent medical help. **Please familiarise yourself with this section of the leaflet and re-read it regularly.**

If you are worried about any unusual symptoms or changes in your health, talk to your doctor, nurse or healthcare provider.

If you experience any of the following serious side effects, seek medical help immediately:

- A serious allergic reaction (it is not known how frequently this occurs)
Symptoms include sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat, skin rash, hives. Allergic reactions may happen soon after injection or can take time to develop in some people. If any of these symptoms appear at any time, even if you have used Sayana Press before, seek medical help immediately.
- A blood clot in the lungs (this occurs **uncommonly** - may affect up to 1 in 100 people)
Symptoms include
 - an unusual sudden cough (which may bring up blood)
 - severe pain in the chest which may increase with deep breathing
 - sudden unexplained breathlessness or rapid breathing
 - severe light headedness or dizziness
 - rapid or irregular heartbeat
 - severe pain in your abdomen
- A blood clot in the leg (it is not known how frequently this occurs)
Symptoms include severe pain or swelling in either of your legs or feet that may be accompanied by tenderness, warmth or discoloured skin
- A blood clot in the eye (it is not known how frequently this occurs)
Symptoms include loss of vision, pain and swelling of the eye especially if sudden
- A stroke (it is not known how frequently this occurs)
Symptoms include
 - weakness or numbness of the face, arm or leg, especially on one side of the body
 - sudden confusion, trouble speaking or understanding
 - sudden trouble seeing in one or both eyes
 - sudden trouble walking, dizziness, loss of balance or coordination
 - sudden, severe or prolonged headache with no known cause
 - loss of consciousness or fainting with or without seizure.

Other side effects include:

Very common: (may affect more than 1 in 10 people)

- Weight decrease
- Weight increase

Common: (may affect up to 1 in 10 people)

- Abdominal pain (cramps)
- Nausea
- Acne
- Amenorrhea (very light or no period)
- Heavy, frequent and/or unexpected bleeding
- Irregular periods
- Period pains
- Breast pain / tenderness
- Depression
- Weakness or tiredness
- Headache
- Injection site reactions (including pain, tenderness, lump, persistent skin indentation/dimpling)
You may feel some soreness or see redness around the injection site immediately after an injection. Mild reactions like this are common. If you get a reaction that worries you in any way, is particularly painful, or does not get better after a short time please talk to your doctor.

- Irritability
- Anxiety
- Decreased sexual feeling
- Vaginal irritation or itching
- Mood changes
- Dizziness
- Back pain
- Pain in limbs
- Abnormal cervical smear

Uncommon: (may affect up to 1 in 100 people)

- Hirsutism (abnormal hairiness)
- Feeling bloated
- Fluid retention
- Vaginal discharge
- Vaginal dryness
- Pain during sexual intercourse
- Ovarian cyst
- Pelvic pain
- Premenstrual syndrome
- Change in breast size
- Milky discharge from breasts in women who are not breastfeeding
- Change in appetite
- Muscle cramps
- Joint pain
- Lack of sleep
- Sleepiness
- Migraine
- Hot flushes
- High blood pressure
- Rapid heart rate
- Varicose veins
- Rash

- Itching
- Hives
- Hair loss
- Skin irritation
- Abnormal liver function test results (blood tests to measure liver injury)
- Bruising
- Facial discoloration
- Inflammation in the veins (felt as tenderness or redness in the affected area)
- Nervousness
- Loss of bone mineral density (a test used to diagnose osteoporosis or weak bones)
- Weakness
- Decreased glucose tolerance (excess sugar level in the blood)

Rare: (may affect up to 1 in 1,000 people)

- Breast cancer
- Fever

Not known: frequency cannot be estimated from the available data

- Osteoporosis (weak bones) including osteoporotic fractures
- Seizures
- Abnormal liver function such as yellowing of the skin or eyes (jaundice)
- Skin stretch marks

Possible effect on your periods

Most women using SAYANA PRESS will experience a change in their bleeding patterns. It is likely that fewer women will experience irregular bleeding, and after 12 months of use 60% will experience little or no bleeding at all.

Possible effect on your bones

SAYANA PRESS works by lowering levels of estrogen and other hormones. However, low estrogen levels can cause bones to become thinner (by reducing bone mineral density). Women who use SAYANA PRESS tend to have lower bone mineral density than women of the same age who have never used it. The effects of SAYANA PRESS are greatest in the first 2-3 years of use. Following this, bone mineral density tends to stabilise and there appears to be some recovery when SAYANA PRESS is stopped. It is not yet possible to say whether SAYANA PRESS increases the risk of osteoporosis (weak bones) and fractures in later life.

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
- Previous low trauma fracture that was not caused by a fall
- Strong family history of osteoporosis

Teenagers (up to 18 years) Normally, the bones of teenagers are rapidly growing and increasing in strength. The stronger the bones are when adulthood is reached, the greater the protection against osteoporosis in later life. Since SAYANA PRESS may cause teenage bones to become thinner at a time when they should be growing, its effect may be particularly important in this age group. Bones

start to recover when SAYANA PRESS is stopped, but it is not yet known whether the bone mineral density reaches the same levels as it would have if SAYANA PRESS had never been used.

You should therefore discuss whether another form of contraception might be more suitable for you with the person who provides your contraception before starting SAYANA PRESS

If you use SAYANA PRESS, it may help your bones if you take regular weight-bearing exercise and have a healthy diet, including an adequate intake of calcium (e.g. in dairy products) and vitamin D (e.g. in oily fish).

Possible risk of cancer

Studies of women who have used a range of medicine-based contraception found that women who used injectable progestogen like SAYANA PRESS for contraception had no increased overall risk of developing cancer of the ovary, womb, cervix, or liver.

Breast cancer is rare under 40 years of age, but the risk increases as a woman becomes older.

There seems to be a slightly increased risk of breast cancer in women who take injectable contraceptives compared to women of the same age who do not use hormonal contraceptives. This small extra risk of developing breast cancer has to be weighed against the known benefits of medicines like SAYANA PRESS. It is not certain whether the injection causes the increased risk of breast cancer. It may be that women receiving the injection are examined more often, so that breast cancer is noticed earlier. The breast cancer seems less likely to have spread when found in women who receive medicines like SAYANA PRESS than in women who do not.

The risk of finding breast cancer is not affected by how long a woman is on the injection, but by the age at which she stops. This is because the risk of breast cancer strongly increases as a woman becomes older. Ten years after stopping hormonal contraceptive injections, the risk of finding breast cancer is the same as for women who have never used hormonal contraceptives.

In 10,000 women who receive injections like SAYANA PRESS for up to 5 years, but stop taking it by the time they are aged 20, it is estimated that less than 1 additional case of breast cancer would be found up to 10 years afterwards, compared with the number found in 10,000 women who had never had the injection.

For 10,000 women who are on injections like SAYANA PRESS for 5 years and stop it by the age of 30, there would be 2 or 3 extra cases of breast cancer found up to 10 years afterwards (in addition to the 44 cases of breast cancer found in 10,000 women in this age group who had never had the injection).

For 10,000 women who take SAYANA PRESS for 5 years and stop it by the age of 40, there would be about 10 extra cases found up to 10 years afterwards (in addition to 160 cases of breast cancer found in 10,000 women in this age group who had never had the injection).

Other risks:

If you develop

- A sudden partial or complete loss of vision, double vision, blood clotting disorders such as pulmonary embolus (blood clot in the lung) or a stroke, you should not receive further injections of SAYANA PRESS
- Migraine, you should consult your doctor before receiving further injections of SAYANA PRESS.
- Jaundice (yellowing of the skin or eyes) you should consult your doctor before receiving further injections of SAYANA PRESS.

Reporting of side effects

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store SAYANA PRESS

- Keep out of sight and reach of children.
- Do not refrigerate or freeze.
- Do not use SAYANA PRESS after the expiry dates stated on the injector, foil pouch and carton after EXP. The expiry date refers to the last day of that month.

Carefully and properly dispose of SAYANA PRESS after use. The injector should NEVER be reused. Do not throw used injectors into household waste. The used injector should not be recapped after use and should be disposed of safely in a special container, in accordance with local authority requirements for the disposal of sharps. Ask your pharmacist for guidance on disposal of medicines.

6. Contents of the pack and other information

What SAYANA PRESS contains

The active substance is medroxyprogesterone acetate (MPA).

The pre-filled injector contains 104mg medroxyprogesterone acetate (MPA) in 0.65 ml.

The other ingredients are macrogol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium chloride, polysorbate 80, monobasic sodium phosphate monohydrate, disodium phosphate dodecahydrate, methionine, povidone, sodium hydroxide and/or hydrochloric acid for pH adjustment and water for injection.

What SAYANA PRESS looks like and contents of the pack

SAYANA PRESS is a white to off-white suspension for subcutaneous injection (an injection given under the skin). It is supplied in a single-dose container in the form of a pre-filled injector. SAYANA PRESS is available with a pack size of one single-dose container.

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	SAYANA PRESS 104 mg/0,65 ml Injektionssuspension
Belgium	SAYANA PRESS 104 mg/0,65 ml suspension for injection
Germany	SAYANA PRESS 104 mg/0,65 ml Injektionssuspension
Hungary, Ireland, Netherlands, United Kingdom	SAYANA PRESS

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