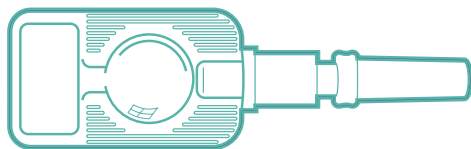


One injection every 13 weeks*

A guide to self-injection with
Sayana® Press (104mg/0.65ml
medroxyprogesterone acetate)



This guide is intended for those who
have been prescribed Sayana® Press

*Each injection provides contraception
for at least 13 weeks (+/-1 week)

If you get any side effects, talk to your doctor,
pharmacist or nurse. This includes any possible
side effects not listed in the package leaflet.
You can also report side effects directly via the
Yellow Card Scheme at yellowcard.mhra.gov.uk.

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

Date of Preparation: September 2020
PP-INT-GBR-0129

First injection: done!

So, what's next?

Welcome to Sayana® Press. Each injection offers long-term contraception cover. This makes contraception one less thing to think about for 13 weeks. Now that your first injection is out of the way, this guide can help you get ready for your future ones. You may have forgotten to ask something at your last appointment, this leaflet can help answer some of those questions.

Don't forget to read the Patient Information Leaflet that came with your medicine. It contains more detailed and important information about Sayana® Press. If you don't have this, your doctor or nurse can give you one at your next appointment.

Have questions or concerns about any part of your medicine?



Let your healthcare professional
know straight away.

Think you have experienced a side effect from your medicine? Report it to the MHRA through the Yellow Card Scheme.



yellowcard.mhra.gov.uk

and contact Pfizer medical information:



01304 616161

What will you find in this guide?

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How Sayana[®] Press works

It is important that you know how your contraception works and also how to use it. Sayana[®] Press (medroxyprogesterone acetate) is a Long-Acting Reversible Contraception (LARC) injection that gives you 13 weeks (+/- 7 days) of effective contraception. There is no need for daily dosing!

Sayana[®] Press does not protect against HIV infection (AIDS) or sexually transmitted diseases (STDs), so a condom may still be needed.

What is Sayana[®] Press and how does it work?

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.

Given by injection under the skin, into the front upper thigh or abdomen, Sayana[®] Press stops pregnancy by preventing an egg (ovum) 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 a pregnancy.

Sayana[®] Press is an effective contraceptive

Sayana[®] Press is 99% effective in preventing pregnancy if used every 13 weeks as recommended. If you miss an injection by a day, don't worry. You have 7 days before you reach 13 weeks and 7 days after to take the injection. Talk to your doctor or nurse if you are more than 7 days late with taking your injection.

Sayana[®] Press is not suitable for some women.

Talk to your doctor or nurse before starting Sayana[®] Press. Your doctor will need to ensure that Sayana[®] Press is the appropriate contraception option for you. Do not use:

- If you are allergic (hypersensitive) to medroxyprogesterone acetate (MPA) or any of the other ingredients of this medicine
- 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 sexual 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.

Using Sayana® Press

To ensure that you are not pregnant at the time of the first injection, it is essential that your first injection is given only during the first 5 days of your normal menstrual cycle.

If you use Sayana® Press after having a baby and you are not breastfeeding, the first injection **MUST** be given within 5 days.

Sayana® Press should be used with caution immediately after childbirth or termination of pregnancy as you may experience heavy or prolonged bleeding.

You want to feel confident each time you inject. Read the instructions for how to self-inject thoroughly. Remember that self-injection is voluntary and optional. If you are unsure, you can always visit your doctor or nurse for your Sayana® Press injection.

These simple step-by-step instructions can help guide you, in addition to the initial training you received from your doctor or nurse and after your first injection. Follow the detailed instructions on how to use your contraception very carefully.

Go to [SayanaAnswers.co.uk](https://www.sayanaanswers.co.uk) to watch an instructional video.

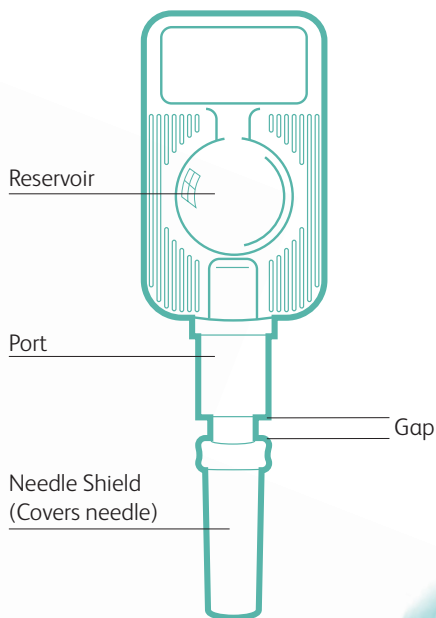


Figure 1: The Injector

Getting ready

- ✓ Ensure medicine is at room temperature.
- ✓ Make sure you have the following:
 - 🔍 Sayana® Press injector in an unopened and undamaged pouch
 - 🔍 Clean cotton pad or tissue
 - 🔍 Container for the used injector
- ✓ Wash your hands



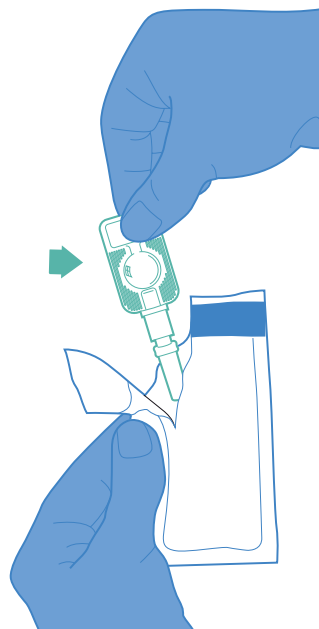
Choosing and preparing the injection area

- ✓ Choose a suitable area for the injection
 - either the abdomen or the front upper thigh
- ✗ Avoid bony areas and navel
- ✗ Avoid areas with scars or skin conditions
- ✗ Change the site with each injection
- ✓ Clean the skin



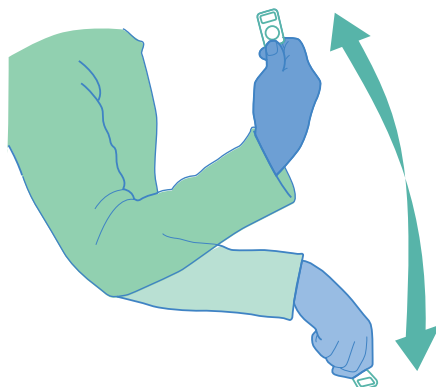
Preparing the injector

- ✓ When you are ready to self-inject, carefully remove the injector.
- ✗ Do not remove the needle shield at this stage
- ✓ Check the injector - discard and use a new one if:
 - ✗ There is no gap between the end of the needle shield and the port
 - ✗ The injector is damaged
 - ✗ Needle shield has come off or is missing



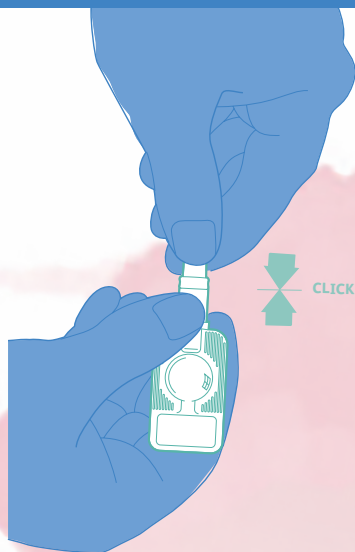
Mixing the medicine

- ✓ Hold injector firmly by the port
- ✓ Shake well for at least 30 seconds. Do not bend
- ✓ Discard and use new injector if:
 - ✗ The liquid does not appear white and uniform
 - ✗ There is any leakage
- ✓ Repeat mixing if injection is delayed



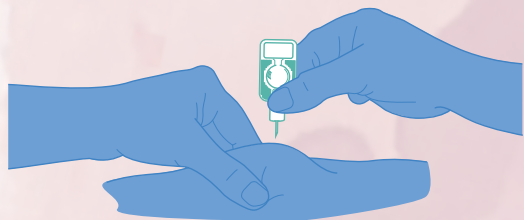
Activating the injector

- ✓ Hold firmly by the port; don't squeeze the reservoir
- ✓ Hold needle shield with other hand
- ✓ Push the needle shield toward port until it stops and you hear a 'click' sound; the injector is now activated
- ✓ Then pull off needle shield and discard it



Self-injecting the dose

- ✓ Gently pinch a large area of skin
- ✓ Insert needle so that port just touches skin
- ✓ Squeeze reservoir slowly to inject medicine (**about 5-7 seconds**)
- ✓ After entire dose has been injected, pull needle out and let go of skin
- ⊘ **Do not replace needle shield**
- ✓ Press area lightly with cotton pad
- ⊘ Do not rub

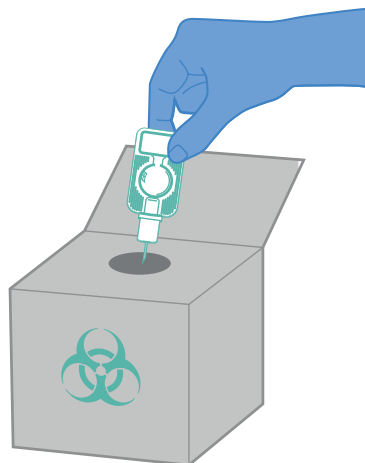


Points to Remember

- It's normal for traces of medicine to be left inside the injector
- If any medicine has leaked, a problem may have occurred; ask your healthcare provider for advice
- If you believe that less than a full dose has been given, ask your healthcare provider about alternative methods of contraception
- Do not inject another dose
- If you experience any symptoms of an allergic reaction, seek medical help immediately
- Monitor the injection area in between injections. If you notice any skin indentation or dimpling, tell your healthcare provider
- Continue to have routine contraceptive checks at least once a year with your healthcare provider or doctor to check if Sayana® Press is still the right option for you

Dispose of the injector

- ✓ After self-injecting, dispose of the used injector in a suitable container, according to your local authority guidance, or as directed by your healthcare provider
- ⊘ Do not re-use



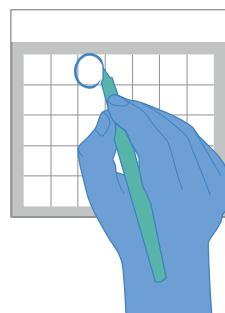
Record the date of your injection

- ✓ Should you wish to continue using Sayana® Press, write down your injection date and the date of your next scheduled injection is 13 weeks later

It is recommended that you continue to visit the clinic as recommended by your doctor, nurse or healthcare provider at least once a year as a minimum so they can check Sayana® Press is still the best option for you. This is also the time 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.

This leaflet can help guide you on your next injection, so make sure to keep it.



Questions

you may have

Can Sayana® Press change my periods?

This may happen. Most women using Sayana® Press will experience a change in their bleeding patterns. According to a clinical study, some women experience irregular bleeding with 60 % of women experiencing little or no bleeding after 12 months of use.

I'm worried about gaining weight, what can I expect?

Every woman reacts to Sayana® Press differently. Studies have shown that after one year's use, 38 % of women put on more than 2.3kgs of weight, 50 % remained within 2.2kgs of their initial body weight and 12 % lost more than 2.2kgs from their initial body weight.

Does Sayana® Press cause any skin reactions?

Injection site reactions (including pain, tenderness, lump, persistent skin indentation/dimpling) may occur. You may feel some soreness or see redness around the injection site immediately after an injection. Mild reactions like this are common and shouldn't be a cause for alarm. 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.

I missed an injection, what should I do?

For Sayana® Press to be most effective it **MUST** be given every 12-13 weeks, and no later than 14 weeks past your last injection.


If you are on holiday or not able to get your next injection before it is due, you should use alternative contraception once the 13 weeks are up and until you can get another injection. You will need to speak to your doctor or nurse before going back on Sayana® Press as they will need to make sure that you are not pregnant before giving you a new prescription.

Does Sayana® Press have an effect on bone health?

Sayana® Press can cause bones to become thinner (by reducing levels of minerals in the bones). These effects are greatest in the first 2-3 years of use. This effect isn't permanent. Bone mineral density tends to stabilise after this period and there appears to be some recovery when the medicine is stopped.

It is not yet possible to say whether Sayana® Press increases the risk of osteoporosis (weak bones) and fractures in later life.

If you are concerned about having any potential risk factors for osteoporosis, please discuss with your healthcare professional.



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

If you use Sayana® Press, it may help your bone health if you take regular weight-bearing exercise and have a healthy diet, making sure you get enough calcium from dairy products and vitamin D from oily fish.

Does Sayana® Press have an effect on bone health in 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.

Teenagers should discuss whether another form of contraception might be more suitable with the person who provides your contraception before starting Sayana® Press.

Is there an increased risk of cancer?

Studies of women who have used different forms of contraception found that women who used Sayana® Press for contraception had no increased overall risk of developing cancer of the ovary, womb, cervix or liver.

Sayana® Press may slightly increase the risk of breast cancer compared with women who have never used it. The risk varies with age. If you would like more details on the risk of breast cancer, please see the leaflet inside the pack or ask your healthcare professional.

Does Sayana® Press cause blood clots?

A clot can occur in a leg vein, signs of which include pain swelling and redness. However, if it moves up the veins into the lungs it can cause chest pain, breathlessness, collapse or even death. Signs of a blood clot in your eye may result in sudden changes in your eyesight (sudden loss or blurred vision). Blood clots can also form in the blood vessels of the brain

Questions

you may have

causing a stroke. Symptoms of a stroke include sudden severe headache, slurred speech, weakness or numbness in the limbs especially on one side. If you do get any of these symptoms, see your doctor immediately and you should not receive any further injections.

Can I use Sayana® Press for more than 2 years?

If you wish to use Sayana® Press for more than 2 years, your healthcare professional may wish to re-evaluate the risks and benefits of using your medicine to make sure that it is still the best option for you.

What if I don't want to continue Sayana® Press?

You can stop using Sayana® Press at any time. If you decide it is no longer for you, remember to use an alternative contraceptive once the 13 weeks are up, unless you want to become pregnant.

Can my Sayana® Press expire?

Each pack of Sayana® Press has an expiry date which you can find printed on the side. The expiry date refers to the last day of that month. Once opened the product should be used immediately or discarded.

What if I decide to have a family?

If you want to get pregnant it is important to understand that fertility can take some time to return once you stop having Sayana® Press injections – on average 5-6 months after the last injection. Over 80 % of women conceive within a year of stopping the injection. It is possible to get pregnant in the first month after missing an injection.

Can I breastfeed and take Sayana® Press?

You can breastfeed and take Sayana® Press 6 weeks after childbirth. It does not prevent the breasts from producing milk. If a baby is exposed to the active ingredient in the breast milk, no harmful effects have been seen in babies and children.

I've just had a baby, how soon can I start Sayana® Press?

If you've had a baby, you can start Sayana® Press 5 days after childbirth if you are not breastfeeding. If you are prescribed Sayana® Press immediately after giving birth you may be more likely to experience heavy or prolonged periods. If you are concerned about this, or any other aspect of your treatment, please see your healthcare professional straight away.

Special warnings & precautions for use

Talk to your healthcare professional if you have had or had in the past any of the following conditions. Some of the conditions can be made worse by taking hormone contraception or might make it less 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
- Psychiatric disorders
- 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

Some women using hormonal contraceptives including SAYANA PRESS have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

- Bone health, blood clots and possible risk of cancer
For information about effects on these areas, please see the “Questions you may have” section and/or read the Patient Information Leaflet.

Possible side-effects

Like all medicines, Sayana® Press can cause side effects

Please familiarise yourself with this section and re-read it regularly.

If you experience any of the serious side effects listed below, or if you notice any side effects not listed here, you should contact your doctor or nurse straight away:

A serious allergic reaction to the medicine or any of its other ingredients:

It is not known how frequently this occurs. However, this can happen even if you have used Sayana® Press before.

A blood clot in the lungs, leg or eye or a stroke (it is not known how frequently this occurs).

Other side effects include:

Common (may affect up to 1 in 10 people): Weight increase, 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); irritability; anxiety; difficulty sleeping; decreased sexual feeling; vaginal irritation or itching; mood changes; dizziness; back pain; pain in limbs; abnormal cervical smear.

Not known (frequency cannot be estimated from the available data): Osteoporosis, seizures, abnormal liver function such as yellowing of the skin or eyes, skin stretch marks.

Please refer to the Patient Information Leaflet you received with your medicine for the full list of all side effects.

If you think you have experienced a side effect from your medicine, you should report it to the MHRA through the Yellow Card Scheme.

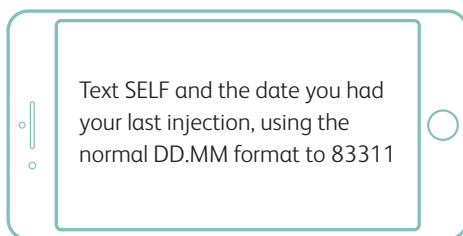
Reporting forms and information can be found at mhra.gov.uk/yellowcard. Adverse events should also be reported to Pfizer Medical Information on 01304 616161

Staying on track

These resources can help you learn even more about Sayana® Press and help you stay on track with your contraception.

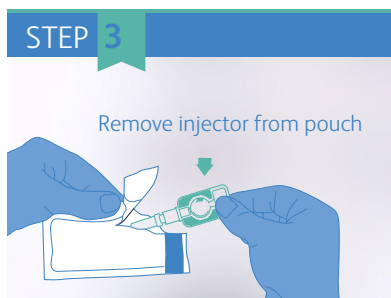
Text message reminders for injections

Please note this is a reminder service only. After each injection you'll need to set a new text reminder.



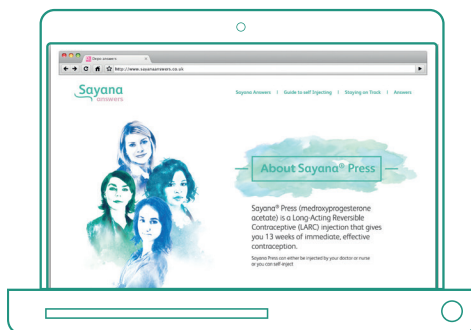
How to self-inject video

View the video at SayanaAnswers.co.uk



SayanaAnswers.co.uk

One place to go for support. Our site features a calendar reminder for your next injection, frequently asked questions, how-to-inject videos and more.



Staying on track

Use this page to record your past and future Sayana® Press injection dates

For effective contraceptive cover, Sayana® Press MUST be given every 12 to 13 weeks, and no later than 14 weeks past your last injection. If you are late in taking your injection, talk to a doctor or nurse about what you should do next.

1st Injection:

2nd Injection due:

2nd Injection:

3rd Injection due:

3rd Injection:

4th Injection due:

4th Injection:

Annual Check-up

It is recommended to see your doctor or nurse at least once a year to check if Sayana® Press is still the right option for you.