

Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.

Package Leaflet: Information for the user

Medroxyprogesterone Acetate

Injection I.P. 104 mg/0.65 ml

SAYANA[®] PRESS

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What SAYANA PRESS (Medroxyprogesterone Acetate) is and what it is used for

SAYANA PRESS (Medroxyprogesterone Acetate) is a contraceptive. It can be used for:

- Long term female contraception.
- Management of endometriosis-associated pain.

2. What you need to know before you use SAYANA PRESS (Medroxyprogesterone Acetate)

Do not use SAYANA PRESS (Medroxyprogesterone Acetate)

- If you are allergic (hypersensitive) to medroxyprogesterone acetate (MPA) or any of the other ingredients of SAYANA PRESS (Medroxyprogesterone Acetate) (listed in section 6)
- 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')

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- If you have or have had a disease affecting the blood vessels of the brain
- If you have had or think you have cancer of the breast
- If you have liver disease
- If you have unexplained vaginal bleeding

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using SAYANA PRESS (Medroxyprogesterone Acetate)

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 (Medroxyprogesterone Acetate) 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, 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
- Family history of breast cancer

Psychiatric disorders

Some women using hormonal contraceptives including SAYANA PRESS (Medroxyprogesterone Acetate) 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.

Effect on your periods

Most women using SAYANA PRESS (Medroxyprogesterone Acetate) will experience a change in their bleeding patterns. It is likely that fewer women will experience irregular bleeding, and most women will experience little or no bleeding at all with long term use.

Effect on your bones

SAYANA PRESS (Medroxyprogesterone Acetate) works by lowering levels of estrogen and other hormones. However, lower estrogen levels can cause bones to become thinner (by reducing bone mineral density). Women who use SAYANA PRESS (Medroxyprogesterone Acetate) tend to have lower bone mineral density than women of the same age who have never used it.

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
- Strong family history of osteoporosis
- Metabolic bone disease

Teenagers (up to 17 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 (Medroxyprogesterone Acetate) 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 (Medroxyprogesterone Acetate) is stopped, but it is not yet known whether the bone mineral density reaches the same levels as it would have if SAYANA PRESS (Medroxyprogesterone Acetate) 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 (Medroxyprogesterone Acetate).

Possible risk of cancer

There is increased risk of breast cancer with hormonal contraceptives including SAYANA PRESS (Medroxyprogesterone Acetate) and if you have a family history of breast cancer or if you have high risk of getting it, the doctor will monitor you more regularly. This risk is greatly increased if you use SAYANA PRESS (Medroxyprogesterone Acetate) for 12 months or longer.

Other risks:

If you develop jaundice (yellowing of the skin or eyes) you should consult your doctor before receiving further injections of SAYANA PRESS (Medroxyprogesterone Acetate).

SAYANA PRESS (Medroxyprogesterone Acetate) does not protect against HIV infection, e.g. AIDS, and other sexually transmitted infections.

Safer sex practices, including correct and consistent use of condoms, reduce the transmission of sexually transmitted infections through sexual contact, including HIV.

You should seek advice from your healthcare professional on how to decrease your risk of catching sexually transmitted infections including HIV.

Other medicines and SAYANA PRESS (Medroxyprogesterone Acetate)

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 (Medroxyprogesterone Acetate), which 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 (Medroxyprogesterone Acetate) as a contraceptive.

Pregnancy and breast-feeding

Do not take SAYANA PRESS (Medroxyprogesterone Acetate) if you are pregnant. If you think you may have become pregnant while using SAYANA PRESS (Medroxyprogesterone Acetate) 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 (Medroxyprogesterone Acetate) 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 information available.

3. How to use SAYANA PRESS (Medroxyprogesterone Acetate)

Method and route of administration

SAYANA PRESS (Medroxyprogesterone Acetate) is injected under the skin into the front upper thigh or abdomen. The injection should be administered by your doctor, nurse, or healthcare provider or when considered appropriate by your doctor, it can be self-injected. You should continue to receive SAYANA PRESS (Medroxyprogesterone Acetate) for as long as instructed by your doctor.

First injection

A dose of 104 mg of SAYANA PRESS (Medroxyprogesterone Acetate) is given subcutaneously (just under the skin), into the front upper thigh or abdomen every 3 months (12 to 14 weeks). SAYANA PRESS (Medroxyprogesterone Acetate) 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 (Medroxyprogesterone Acetate) after having a baby and you are not breastfeeding, the first injection **MUST** be given within 5 days.

Further injections

Further doses of SAYANA PRESS (Medroxyprogesterone Acetate) 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 receive your next injections at the right time.

If you miss an injection of SAYANA PRESS (Medroxyprogesterone Acetate)

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 receive your next injection of SAYANA PRESS (Medroxyprogesterone Acetate) 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 (Medroxyprogesterone Acetate) 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 (Medroxyprogesterone Acetate). 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 (Medroxyprogesterone Acetate). It is possible to get pregnant in the first month after missing an injection.

4. Possible side effects

Like all medicines, SAYANA PRESS (Medroxyprogesterone Acetate) 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 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.
- A blood clot in the lungs (it is not known how frequently this occurs)
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:

Common: (>1%)

- Weight increase
- Abdominal pain (cramps)
- Urinary tract infections
- Nausea
- Acne
- Amenorrhea (very light or no period)
- Heavy, frequent and/or unexpected bleeding
- Irregular periods
- Period pains
- Breast pain / tenderness
- Depression
- Tiredness
- Headache
- Injection site reactions (including pain, tenderness, nodule, lump, lipodystrophy, discoloration, persistent atrophy/indentation/dimpling)
- Irritability
- Anxiety
- Decreased sexual feeling
- Vaginal irritation or itching
- Dizziness
- Back pain

Uncommon: (<1%)

- Drug allergy
- Breast lump
- Reduced red blood cells (Anemia)
- Feeling bloated
- Weight decrease
- Fluid retention
- Pain during sexual intercourse
- Ovarian cyst
- Pelvic pain
- Premenstrual syndrome
- Change in breast size
- Milky discharge from breasts in women who are not breastfeeding
- Tingling, pins and needles
- Asthma
- Breathlessness, difficulty breathing
- Sleepiness
- Dry skin
- Vertigo (a spinning sensation)
- Hot flushes

- Diarrhea
- Chest pain
- Rapid heart rate
- Rash
- Itching
- Hives
- Skin irritation

Not known (Postmarketing Experience): frequency cannot be estimated from the available data

- Severe allergic reaction
- Clots in the arteries of lungs and in deep veins
- Inflammation of veins (Thrombophlebitis)
- Osteoporosis (weak bones) including osteoporotic fractures
- Unexpected pregnancy; thickening of uterus lining (uterine hyperplasia)
- Increased body odour
- Hoarseness
- Gastrointestinal disturbances
- Armpit swelling
- Chills
- Thirst

5. How to store SAYANA PRESS (Medroxyprogesterone Acetate)

Store below 30°C.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What SAYANA PRESS (Medroxyprogesterone Acetate) contains

The active substance is medroxyprogesterone acetate (MPA).

The pre-filled single use drug delivery system of SAYANA PRESS (Medroxyprogesterone Acetate) contains 104 mg medroxyprogesterone acetate (MPA) in 0.65 ml.

The other ingredients are methyl paraben, propyl paraben, sodium chloride, Polyethylene Glycol 3350, polysorbate 80, monobasic sodium phosphate, disodium phosphate, dodecahydrate methionine, povidone K 17 PF, sodium hydroxide or hydrochloric acid for pH adjustment and water for injection.

What SAYANA PRESS (Medroxyprogesterone Acetate) looks like and contents of the pack

SAYANA PRESS (Medroxyprogesterone Acetate) is white to off-white homogeneous suspension containing medroxyprogesterone acetate (MPA), a derivative of progesterone, as its active ingredient. MPA is a white to off-white, odorless crystalline powder that is stable in air and that melts between 205°C and 209°C. It is freely soluble in chloroform, soluble in

acetone and dioxane, sparingly soluble in alcohol and methanol, slightly soluble in ether, and insoluble in water.

Contents of the pack:

DMPA-SC 104 mg/0.65 ml is packaged in an all in one, pre-fillable single use drug delivery system designed for subcutaneous injection. Prior to use the injection is activated by piercing of the membrane barrier by the double pointed cannula. The dose is then delivered by depressing the unit reservoir. After the dose is expressed, the collapsed reservoir and a one-way valve inhibit refill, preventing re-use.

Each DMPA-SC 104 mg/0.65 ml pre-filled single use injection system is packaged in a foil laminate pouch.

Manufacturer:

Pfizer Manufacturing Belgium NV, Rijksweg 12, Puurs- Sint Amands, 2870, Belgium.

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