WHO-PQ recommended clinical and preclinical information for the patient

This information reflects the recommendations of current WHO guidelines and the scope of WHO's prequalification programme.

Information for the patient

Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection*
Medroxyprogesterone acetate

Carers or parents looking after the person who takes this medicine should use this information to give the medicine correctly and take note of the warnings and side effects

1. What Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection is and what it is used for

Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection contains the active substance medroxyprogesterone acetate, which is like progesterone, a natural hormone. It is made up as an injection that releases the hormone into the bloodstream over several weeks. Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection is also called 'depot medroxyprogesterone acetate' or 'DMPA'.

Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection prevents an egg from developing fully and being released into the womb. This means that sperm cannot fertilise the egg to start a pregnancy. Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection also causes changes to the lining of womb that make pregnancy less likely. Moreover, by making the entrance to the womb thicker, it makes it more difficult for sperm to enter the womb.

Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection is used for long-term contraception in women.

It can also be used for short-term contraception to cover specific periods when:

- your partner is awaiting vasectomy to become effective;
- you are awaiting sterilisation;
- you are awaiting immunisation against rubella to become effective.

2. What you need to know before you take Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection

Do not use Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection:

- If you are allergic (hypersensitive) to medroxyprogesterone acetate or to any of the other ingredients (listed in section 6).
- If you have or have had cancer of the breast.
- If you have abnormal bleeding from your vagina.
- If you have severe liver disease.
- If you have high blood pressure.
- If you have had diabetes for longer than 20 years or complications of the diabetes affecting your blood vessels, kidneys, nerves or eyes
- If you have ever had heart disease (e.g. myocardial infarction) or stroke because of blocked blood vessels
- If you have or have had arterial thrombosis (blocked blood vessels carrying blood from the heart)
- If you have acute deep venous thrombosis or pulmonary embolism (which are caused by blockage in blood vessels returning blood to the heart)
- If you have systemic lupus erythematosus.
- If you have meningioma or have ever had meningioma (usually benign tumour of the tissue surrounding the brain and spinal cord).

Check with your health care provider if you have any of these conditions.

* Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

Warnings and precautions

Your health care provider will ask about your and your family's health, check your blood pressure and check that you are not pregnant. You may also have other checks depending on your health and any worries you might have.

Tell your health care provider if you are using medicines such as steroids, epilepsy medicines and thyroid hormones.

It is important to tell your health care provider if you have or have had any of the following conditions:

- Migraine headaches
- Diabetes or if somebody in the family has diabetes
- Severe pain or swelling in the calf
- Problems with your eyesight for example a sudden partial or complete loss of vision or double vision
- Depression
- Problems with your liver or liver disease
- Problems with your kidneys or kidney disease
- Heart disease or cholesterol problems including any family history
- Abnormal pregnancy
- Asthma
- Epilepsy

Your health care provider will then discuss with you whether Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection is suitable for you or recommend another method of contraception.

Tell your health care provider at once if you get a blood clot in the lung or leg (see also 'Get medical help immediately', below in section 4) or if you have a 'mini-stroke' (transient ischaemic attack) or a stroke.

Use of contraceptives like Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection has been linked to the development of meningioma, which is a growth in the tissue surrounding the brain and spinal cord. Meningioma does not usually spread. The risk of meningioma increases especially when Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection is used for several years. Tell your health care provider at once if you get:

- vision problems (like seeing double or blurriness)
- hearing problems (including hearing sounds continuously)
- smell disturbances
- memory loss
- headaches that are getting worse
- fits (seizures)
- weakness in your arms or legs.

These may be signs of meningioma and your health care provider may wish to stop Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection.

Psychiatric disorders

Depression or depressed mood may occur in women using Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection. Depression can be serious and may sometimes lead to suicidal thoughts. If you get mood changes and depressive symptoms contact your health care provider for advice as soon as possible.

Possible effects on your bones

Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection works by lowering levels of oestrogen and other hormones. However, lower oestrogen levels can cause bones to become thinner (by reducing bone mineral density). Women who use Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection tend to have lower bone mineral density than women of the same age who have never used it. The effects of Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection 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 of bone density when Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection is stopped. It is not yet possible to say whether Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection increases the risk of osteoporosis (weak bones) and fractures in later life (after the menopause).

The following are risk factors in the development of osteoporosis in later life. You should discuss with your health care provider 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.

Cervical smear testing

Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection may affect the results of a cervical smear and some laboratory tests. Tell your health care provider that you are using Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection before you have any medical tests.

Protection against sexually transmitted infections

Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection does not protect against HIV infection and other sexually transmitted infections. Safer sex practice, including correct and consistent use of condoms, reduces the transmission of sexually transmitted infections, including HIV. Ask your health care provider about how to decrease your risk of catching sexually transmitted infections.

Abscess formation at the injection site

If Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection is not injected correctly, there is a risk of pus formation (abscess) at the site of injection, which may require medical or surgical attention.

Other medicines and Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection

Tell your health care provider:

- If you are taking, have recently taken or might take any other medicines.
- If you are taking a medicine called aminoglutethimide or medicines that reduce blood clots (anticoagulants).

Always tell your health care provider who treats you that you are using Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection as a contraceptive because medicines can sometimes interact with each other.

Laboratory tests

Using Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection may change the results of some laboratory tests. Tell your health care provider that you are using Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection if you have medical tests.

Pregnancy, breast-feeding and fertility

Pregnancy

Your health care provider will check that you are not pregnant before giving you the first injection Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection and also if an injection is overdue.

Breast-feeding

Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection does not prevent the breast from producing milk so mothers can use it, starting 6 weeks after birth of the baby. Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection given to a mother does not have ill effects on the breast-feeding baby.

Fertility

Your usual level of fertility should return when the effect of the injection has worn off. This takes different amounts of time in different women and does not depend on how long you have been using Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection.

Driving and using machines

Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection is not likely to affect your ability to drive or operate machinery.

However, make sure you feel well enough to take on any skilled tasks.

3. How to take Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection

Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection will be given to you by your health care provider.

Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection is given every 13 weeks as a single injection under the skin (subcutaneous) of 0.65 mL (104 mg medroxyprogesterone acetate) into back of the upper arm or the abdomen or the front of the thigh. The injection is given during the first 7 days after the beginning of a normal menstrual period.

Following childbirth, when you start Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection depends on when your monthly bleeding returns, but in general:

- If you are fully (or nearly fully) **breast-feeding**, Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection can be started between 6 weeks and 6 months of the birth of your baby if your monthly bleeding has not returned
- If you are **partially breast-feeding**, Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection can be started 6 weeks after the birth of your baby
- If you are **not breast-feeding**, Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection can be started within 4 weeks of the birth of your baby.

Your health care provider will tell you when you can start Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection in other circumstances (e.g. after a miscarriage or when switching from another contraception method).

Provided the injection is started at the right time, then you are protected from pregnancy straight away and there is no need to take extra precautions.

Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection works for 13 weeks. It must be given every 13 weeks to make sure you have effective contraceptive cover. Make sure that you or your health care provider makes your next appointment for 13 weeks' time.

If you do not get an injection of Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection at the right time

If you are late getting your next injection (it is longer than 13 weeks between injections), there is a greater risk that you could become pregnant. Ask your health care provider when you should receive your next injection of Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection and which type of contraception you should use in the meantime.

If you have any questions on the use of this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection can cause side effects although not everybody gets them.

Get medical help immediately if you notice any of the following side effects:

- Allergic (hypersensitivity) reaction, likely to be a rare effect. Symptoms include sudden skin rash, swelling of the face, lips, tongue or throat, wheezing or difficulty in breathing.
- A blood clot in the leg (this occurs rarely—may affect up to 1 in 1000 people)
  Deep vein thrombosis (DVT) is a condition in which blood clot forms in one of your deep veins, usually in your leg. These are symptoms of a **deep-vein thrombosis (DVT):**
  - pain, tenderness or swelling in your calf, ankle or foot
  - painful or inflamed veins in your leg
  - difficulty putting full weight on the affected leg
  - purple discoloration of the skin of the leg or the skin becomes red and warm to touch.
- A blood clot in the brain which can lead to stroke (frequency unknown). These are the symptoms of a blood clot in the brain:
  - 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
  - loss of consciousness or fainting with or without seizure (fit)
- 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

Other side-effects include:
Common: (may affect up to 1 in 10 people)

- Weight increase (see also ‘Weight changes’, below)
- Abdominal (belly) pain
- Nausea
- Acne
- Amenorrhea (very light or no period)
- Heavy, frequent or unexpected bleeding
- Irregular periods
- Period pains
- Breast pain or tenderness
- Depression
- Tiredness
- Headache
- Injection site reactions (including pain, tenderness, lump, persistent skin indentation/dimpling), see below
- Irritability
- Anxiety

- Difficulty sleeping
- Decreased sexual feeling (libido)
- Vaginal irritation or itching
- Vaginal or urinary tract infection
- Mood changes
- Dizziness
- Back pain
- Pain in limbs
- Abnormal cervical smear

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

- Drug allergy
- Feeling bloated
- Fluid retention
- Vaginal discharge
- Vaginal dryness
- Pain during sexual intercourse
- Ovarian cyst
- Pelvic pain
- Premenstrual syndrome
- Breast enlargement
- Milky discharge from breasts (when not breast-feeding)
- Reduced milk production when breast-feeding
- Change in appetite
- Muscle cramps
- Joint pain
- Sleepiness
- Migraine
- Vertigo (a spinning sensation)
- Hot flushes
- Fever
- High blood pressure
- Rapid heart rate
- Varicose veins
- Rash
- Itching
- Hives
- Hirsutism (abnormal hairiness)
- Hair loss
- Skin irritation
- Bruising
- Skin colour changes, especially in areas exposed to the sun
- 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)
- Decreased glucose tolerance (excess sugar level in the blood)
- Emotional disturbance
- Inability to achieve a sexual climax
- Abnormal liver function test results (blood tests to check for liver injury)

- Numbness
- Breathing difficulty

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

- Breast cancer (but see 'Possible risk of cancer', below)
- Jaundice (yellowing of the skin, of the whites of the eyes and under the nails)
- Voice changes
- Weakness, lack of energy
- Weight decrease (see also 'Weight changes', below)
- Injection site discolouration
- Anaemia
- Blood disorder
- Fainting
- Rectal bleeding
- Abnormal distribution of fat
- Skin hardening and tightening
- Excessive thickening of the lining of the womb
- Breast shrinkage
- Bloody discharge from nipples
- Vaginal cyst
- Lack of return to fertility
- Sensation of pregnancy
- Thirst
- Facial nerve paralysis
- Lymph node swelling in the armpit

Frequency cannot be estimated from the available data

- Usually benign tumour of the tissue surrounding the brain and spinal cord (meningioma) (see section 2 'Warnings and precautions')
- Cervical cancer (but see 'Possible risk of cancer', below)
- Osteoporosis (weak bones) including osteoporotic fractures (see 'Possible effects on your bones', above)
- Seizures (fits)
- Skin stretch marks
- Asthma
- Hoarseness
- Chills

Effects on your periods

Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection usually disturbs the pattern of a woman's monthly period. After the first injection you are likely to have irregular, possibly prolonged bleeding or spotting. This is quite normal and nothing to worry about.

Some women have no bleeding after the first injection. After 4 injections, periods stop completely in most women. Not having periods is nothing to worry about.

If you have very heavy or prolonged bleeding, talk to your health care provider who may offer treatment. When you stop taking Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection, your periods will return to normal in a few months.

Possible risk of cancer
Studies of women who have used different forms of contraception found that women who used Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection, for contraception had no increase in overall risk of developing cancer of the ovary, womb, cervix or liver.

A few studies suggest a slightly increased risk of cervical cancer among women using depot medroxyprogesterone acetate for 5 years or longer. However, cervical cancer is caused by long-term infection with human papillomavirus, and it cannot develop because of depot medroxyprogesterone acetate alone.

Injection site reactions
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, is particularly painful, does not get better after a short time, or there is swelling and a build-up of pus at the site of injection, tell your health care provider.

Weight changes
Some women gained weight while using Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection. Studies show that over the first 1–2 years of use, the average weight gain was 2–4 kg. Women completing 4–6 years gained on average 6–7.5 kg.

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection

Product specific information on the storage conditions is shown in the product information as approved by the reference authority, stated in WHOPAR part 1.

6. Contents of the pack and other information

What Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection contains

What Medroxyprogesterone acetate 104 mg/0.65 mL suspension for injection looks like and contents of the pack

Supplier and Manufacturer

This leaflet was last revised in January 2026

Product specific information on the composition, visual appearance of the formulation, appearance and size of packs as well as on the supplier, is shown in the product information as approved by the reference authority, stated in WHOPAR part 1.

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