WHO-PQ recommended clinical and preclinical information for the patient

This information focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.[*]

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

[*]https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[RH018 trade name][†]
Medroxyprogesterone acetate

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

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

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Medroxyprogesterone acetate 150 mg/mL suspension for injectionis and what it is used for

Medroxyprogesterone acetate 150 mg/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 150 mg/mL suspension for injection is also called ‘depot medroxyprogesterone acetate’ or ‘DMPA’.

This medicine prevents an egg from developing fully and being released into the womb. This means that sperm cannot fertilise the egg to start a pregnancy. This medicine 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.

This medicine 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.

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency’s responsibility.

2. What you need to know before you take [RH018 trade name]

Do not use [RH018 trade name]:

- If you are allergic (hypersensitive) to medroxyprogesterone acetate or to any of the other ingredients (listed in section 6).
- If you have had, or think you may have, cancer of the breast or genital organs.
- 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.
- 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.

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 this medicine 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 this medicine 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 this medicine 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 [RH018 trade name].

Psychiatric disorders

Depression or depressed mood may occur in women using [RH018 trade name]. 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

This medicine 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 this medicine tend to have lower bone mineral density than women of the same age who have never used it. The effects of this 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 this medicine is stopped. It is not yet possible to say whether this medicine 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 healthcare provide 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

This medicine may affect the results of a cervical smear and some laboratory tests. Tell your health care provider that you are using Medroxyprogesterone acetate 150 mg/mL suspension for injection before you have any medical tests.

Protection against sexually transmitted infections

This medicine 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.

Other medicines and [RH018 trade name]

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 this medicine as a contraceptive because medicines can sometimes interact with each other.

Pregnancy, breast-feeding and fertility

Pregnancy

Your health care provider will check that you are not pregnant before giving you the first injection of this medicine and also if an injection is delayed longer than 12 weeks.

Breast-feeding

This medicine does not prevent the breast from producing milk so mothers can use it, starting 6 weeks after birth of the baby. This medicine 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 150 mg/mL suspension for injection.

3. How to take [RH018 trade name]

Medroxyprogesterone acetate 150 mg/mL suspension for injection will be given to you by your health care provider.

Medroxyprogesterone acetate 150 mg/mL suspension for injection is given every 12 weeks as a single intramuscular injection of 1 mL (150 mg medroxyprogesterone acetate) into the buttock or upper arm. The injection is given during the first 7 days after the beginning of a normal menstrual period.

Following childbirth, when you start this medicine depends on when your monthly bleeding returns, but in general:

- If you are fully (or nearly fully) **breast-feeding**, Medroxyprogesterone acetate 150 mg/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 150 mg/mL suspension for injection can be started 6 weeks after the birth of your baby
- If you are **not breast-feeding**, Medroxyprogesterone acetate 150 mg/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 150 mg/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 150 mg/mL suspension for injection works for 12 weeks. It must be given every 12 weeks to make sure you have effective contraceptive cover. Make sure that you or your health care provider makes your next appointment for 12 weeks' time.

If you do not get an injection of Medroxyprogesterone acetate 150 mg/mL suspension for injection at the right time

If you are late getting your next injection (it is longer than 12 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 this medicine 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, this medicine 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 very 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 lungs (this occurs rarely—may affect up to 1 in 1000 people)
  Symptoms include:
  - Shortness of breath
  - Breath-related chest pains
  - Coughing up blood
- 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):**
  - You have pain, tenderness or swelling in your calf, ankle or foot
  - You have painful or inflamed veins in your leg
  - You find it difficult to put full weight on the affected leg
  - You have purple discoloration of the skin of the leg, or the skin becomes red and warm to touch.
- Jaundice (yellowing of the skin or the whites of the eyes).

Women who use this medicine may have lower bone mineral density (a measure of bone strength) than women of the same age who have never used it.

Other side-effects include:

Very common: may affect more than 1 in 10 people

- nervousness
- headache
- belly pain or discomfort
- weight increase or decrease

Common: may affect up to 1 in 10 people

- depression
- decreased libido (reduced sex drive)
- dizziness
- feeling sick (nausea)
- feeling bloated
- hair loss
- acne
- rash
- back pain
- pain in arms and legs
- vaginal discharge
- breast tenderness
- difficult or painful period
- urinary tract infection
- oedema/fluid retention
- weakness

Uncommon: may affect up to 1 in 100 people

- appetite increased or decreased
- difficulty sleeping
- convulsions (fits)
- drowsiness
- tingling
- breathing difficulty
- hot flush
- liver disorder
- facial hair growth
- nettle rash or hives
- itchy skin
- temporary brown patches
- unexpected or unusual vaginal bleeding or spotting
- milky discharge from the breast when not pregnant or breast-feeding
- pelvic pain
- painful intercourse
- prevention of lactation
- chest pain

Rare: may affect up to 1 in 1000 people

- breast cancer
- reduction in red blood cell (which can cause tiredness and pale appearance)
- blood disorder
- difficulty reaching orgasm
- behavior change
- mood change
- irritability
- anxiety
- migraine
- paralysis
- fainting
- feeling of dizziness or spinning
- rapid heartbeat
- high blood pressure
- blood clots (which can cause deep vein thrombosis and blocked vessels in the lungs)
- varicose veins
- rectal bleeding
- digestive disorder
- liver enzyme disorder
- inflammation of the skin
- fat build-up and scarring at injection site
- skin hardening and tightening
- stretch marks
- joint pain
- muscle cramps
- decreased bone density (osteoporosis) which may lead to fractures
- premenstrual syndrome
- vaginal pain or inflammation
- vaginal dryness
- ovarian or vaginal cyst

- stopping of your periods or longer breaks between them
- uterine bleeding or excessive bleeding
- periods with abnormally heavy or prolonged bleeding
- change in breast size
- breast pain
- breast lump
- nipple bleeding
- excessive thickening of the lining of the womb
- delayed egg release with longer menstrual cycles (periods)
- feel pregnant
- fever
- tiredness
- injection site pain or tenderness
- injection site lump or dimple
- feeling thirsty
- hoarseness
- facial nerve paralysis
- lumps under the armpit
- high blood sugar levels
- abnormal smear

Frequency not known

- cervical cancer
- asthma
- chills
- benign tumour of the tissue surrounding the brain and spinal cord (meningioma)

Possible effect on your periods

This medicine 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 [RH018 trade name], your periods will return to normal in a few months.

Possible effects on your bones

This medicine can slightly reduce the strength of your bones (by decreasing bone mineral density). This may increase the risk of fractures later, after menopause. However, the bone strength may recover after stopping [RH018 trade name].

Possible risk of cancer

Studies of women who have used different forms of contraception found that women who used Medroxyprogesterone acetate 150 mg/mL suspension for injection for contraception had no increase in overall risk of developing cancer of the ovary, womb, cervix or liver.

Risk of an abscess at the injection site

As with any intramuscular injection, there is a risk of an abscess forming at the site of injection. This may require medical or surgical attention.

Possible risk of weight gain

Some women gained weight while using this medicine. 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.

5. How to store [RH018 trade name]

6. Contents of the pack and other information

What Medroxyprogesterone acetate 150 mg/mL suspension for injection contains

- The active ingredient is medroxyprogesterone acetate. Each mL of suspension contains 150 mg of medroxyprogesterone acetate.
- The other ingredients of this medicine are:

What Medroxyprogesterone acetate 150 mg/mL suspension for injection looks like and contents of the pack

Supplier and Manufacturer

Supplier ***Manufacturer***

For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in July 2025.

Detailed information on this medicine is available on the World Health Organization (WHO) website: https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products