WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

This patient information leaflet 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

[RH084 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 get 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 [RH084 trade name] is and what it is used for

[RH084 trade name] 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. [RH084 trade name] is also called ‘depot medroxyprogesterone acetate’ or ‘DMPA’.

[RH084 trade name] prevents an egg from developing fully and being released into the womb. This means that sperm cannot fertilise the egg to start a pregnancy. [RH084 trade name] 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.

[RH084 trade name] 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 are given [RH084 trade name]

Do not use [RH084 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.

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

- 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 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 [RH084 trade name] is suitable for you or recommend another method of contraception.

The use of contraceptives like [RH084 trade name] 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 [RH084 trade name] 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 [RH084 trade name].

Psychiatric disorders

Depression or depressed mood may occur in women using [RH084 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

[RH084 trade name] 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 [RH084 trade name] tend to have lower bone mineral density than women of the same age who have never used it. The effects of [RH084 trade name] 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 [RH084 trade name] is stopped. It is not yet possible to say whether [RH084 trade name] 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

[RH084 trade name] may affect the results of a cervical smear and some laboratory tests. Tell your health care provider that you are using [RH084 trade name] before you have any medical tests.

Protection against sexually transmitted infections

[RH084 trade name] 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 [RH084 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 clot(anticoagulants).

Always tell your health care provider who treats you that you are using [RH084 trade name] 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 [RH084 trade name] and also if an injection is delayed longer than 12 weeks.

Breast-feeding

[RH084 trade name] does not prevent the breast from producing milk so mothers can use it, starting 6 weeks after birth of the baby. [RH084 trade name] 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 [RH084 trade name].

Driving and using machines

[RH084 trade name] may cause headaches and dizziness. Do not operate machines or drive if you feel dizzy after taking [RH084 trade name].

[RH084 trade name] contains methyl paraben and propyl paraben

Each vial contains methyl paraben and propyl paraben which may cause allergic reactions (possibly delayed), and exceptionally bronchospasm (difficulty breathing caused by narrowing of the airways).

3. How [RH084 trade name] is given

[RH084 trade name] will be given to you by your health care provider.

[RH084 trade name] 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 [RH084 trade name] depends on when your monthly bleeding returns, but in general:

- If you are fully (or nearly fully) **breast-feeding**, [RH084 trade name] 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**, [RH084 trade name] can be started 6 weeks after the birth of your baby
- If you are **not breast-feeding**, [RH084 trade name] can be started within 4 weeks of the birth of your baby.

Your health care provider will tell you when you can start [RH084 trade name] 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.

[RH084 trade name] 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 [RH084 trade name] 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 [RH084 trade name] 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, [RH084 trade name] 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 [RH084 trade name] 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

[RH084 trade name] 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 [RH084 trade name], your periods will return to normal in a few months.

Possible effects on your bones

[RH084 trade name] 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 [RH084 trade name].

Possible risk of cancer

Studies of women who have used different forms of contraception found that women who used [RH084 trade name], 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 [RH084 trade name]. 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 [RH084 trade name]

Do not store above 30ºC. Do not freeze. Store vials in the cartons to protect from light.

Keep this medicine out of the sight and reach of children.

This medicine must not be used after the expiry date stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicine must not be used if description of the visible signs of deterioration.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [RH084 trade name] contains

- The active ingredient is medroxyprogesterone acetate
- The other ingredients of [RH084 trade name] are polyethylene glycol 3350, polysorbate 80 (tween 80), sodium chloride (injectable grade), methyl paraben, propyl paraben, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), nitrogen (injectable grade, for air displacement) and water for injection.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

What [RH084 trade name] looks like and contents of the pack

[RH084 trade name] is a white to off-white sterile suspension for injection.

[RH084 trade name] is packed in Type-1 (3mL) clear glass vial, sealed with a 13 mm grey chlorobutyl rubber stopper and a red flip–off aluminium seal, containing 1 mL white to off-white suspension. Available in packs of 1's and 20's.

Supplier and Manufacturer

Supplier

Incepta Pharamceuticals Limited
40, Shahid Tajuddin Ahmed Sarani
Tejgaon I/A, Dhaka-1208
Bangladesh
Tel: +880-2-8891688-703
Fax: +880-2-8891190
Email: enquiry@inceptapharma.com

Manufacturer

Incepta Pharmaceuticals Limited
Unit-1, Injectable Potent Drug (IPD)
Krishnapura, Sahabelishor
Dhamrai, Dhaka
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Tel: +880222-4498137
Fax: +880222-4498135
Email: enquiry@inceptapharma.com

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

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

The following information is intended for health care providers only: (For further information, consult the Summary of Product Characteristics.)

Dosage:
Each mL of suspension contains 150 mg medroxyprogesterone acetate. The sterile aqueous suspension of [RH084 trade name] should be vigorously shaken just before use to ensure that the dose being given represents a uniform suspension of [RH084 trade name]. Doses should be given by deep intramuscular injection into the buttock or arm.
Care should be taken to ensure that the depot injection is given into the muscle tissue, preferably the gluteus maximus, but other muscle tissue such as the deltoid may be used and the site of injection should be cleansed using standard methods prior to administration of the injection.

Assembly of syringe for single use:
1. Remove tip cap.

2. Position needle using aseptic technique.
3. Remove needle shield. The syringe is now ready for use.

Further doses: These should be given at 12 week intervals, however, as long as the injection is given no later than five days after this time, no additional contraceptive measures (e.g. barrier) are required.
(NB for partners of men undergoing vasectomy a second injection of 150 mg i.m. 12 weeks after the first may be necessary in a small proportion of patients where the partner's sperm count has not fallen to zero.) If the interval from the preceding injection is greater than 12 weeks for any reason, then pregnancy should be excluded before the next injection is given and the patient should use additional contraceptive measures (e.g. barrier) for fourteen days after this subsequent injection.

Administration:

Adults

First injection: To provide contraceptive cover in the first cycle of use, an injection of 150 mg i.m. should be given during the first five days of a normal menstrual cycle. If the injection is carried out according to these instructions, no additional contraceptive cover is required.

Postpartum: To increase assurance that the patient is not pregnant at the time of first administration, this injection should be given within 5 days postpartum if not breast-feeding.

There is evidence that women prescribed [RH084 trade name] in the immediate puerperium can experience prolonged and heavy bleeding. Because of this, the drug should be used with caution in the puerperium. Women who are considering use of the product immediately following delivery or termination should be advised that the risk of heavy or prolonged bleeding may be increased.

Health care providers are reminded that in the non-breast-feeding postpartum patient, ovulation may occur as early as week 4. If the puerperal woman will be breast-feeding, the initial injection should be given no sooner than six weeks postpartum, when the infant's enzyme system is more fully developed. Further injections should be given at 12 week intervals.

Paediatric population (12-18 years): [RH084 trade name] is not indicated before menarche. Data in adolescent females (12-18 years) is available. Other than concerns about loss of BMD, the safety and effectiveness of [RH084 trade name] is expected to be the same for adolescents after menarche and adult females.

Switching from other Methods of Contraception: [RH084 trade name] should be given in a manner that ensures continuous contraceptive coverage. This should be based upon the mechanism of action of other methods (e.g. patients switching from oral contraceptives should have their first injection of [RH084 trade name] within 7 days of taking their last active pill).

Hepatic Insufficiency: The effect of hepatic disease on the pharmacokinetics of [RH084 trade name] is unknown. As [RH084 trade name] largely undergoes hepatic elimination it may be poorly metabolised in patients with severe liver insufficiency (see Contraindications).

Renal Insufficiency: The effect of renal disease on the pharmacokinetics of [RH084 trade name] is unknown. No dosage adjustment should be necessary in women with renal insufficiency, since [RH084 trade name] is almost exclusively eliminated by hepatic metabolism.