

## **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.*

## Information for the patient

**[RH106 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 [RH106 trade name] is and what it is used for
2. What you need to know before you take [RH106 trade name]
3. How to take [RH106 trade name]
4. Possible side effects
5. How to store [RH106 trade name]
6. Contents of the pack and other information

#### **1. What [RH106 trade name] is and what it is used for**

[RH106 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. [RH106 trade name] is also called ‘depot medroxyprogesterone acetate’ or ‘DMPA’.

[RH106 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. [RH106 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.

[RH106 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 [RH106 trade name]**

##### **Do not use [RH106 trade name]:**

- 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.

---

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

- 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.

### **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 [RH106 trade name] 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 [RH106 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 [RH106 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 [RH106 trade name].

### **Psychiatric disorders**

Depression or depressed mood may occur in women using [RH106 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**

[RH106 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 [RH106 trade name] tend to have lower bone mineral density than women of the same age who have never used it. The effects of [RH106 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 [RH106 trade name] is stopped. It is not yet possible to say whether [RH106 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 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**

[RH106 trade name] may affect the results of a cervical smear and some laboratory tests. Tell your health care provider that you are using [RH106 trade name] before you have any medical tests.

### **Protection against sexually transmitted infections**

[RH106 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.

### **Abscess formation at the injection site**

If [RH106 trade name] 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 [RH106 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 [RH106 trade name] as a contraceptive because medicines can sometimes interact with each other.

### **Laboratory tests**

Using [RH106 trade name] may change the results of some laboratory tests. Tell your health care provider that you are using [RH106 trade name] 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 [RH106 trade name] and also if an injection is overdue.

### *Breast-feeding*

[RH106 trade name] does not prevent the breast from producing milk so mothers can use it, starting 6 weeks after birth of the baby. [RH106 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 [RH106 trade name].

## **Driving and using machines**

[RH106 trade name] 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.

## **[RH106 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 [RH106 trade name] is given**

Your health care provider will inject [RH106 trade name]. If it is right for you, the health care provider may teach you how to inject [RH106 trade name]. You can find information on how to inject [RH106 trade name] yourself in section 6 of this leaflet under 'Instructions for use'.

[RH106 trade name] 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 [RH106 trade name] depends on when your monthly bleeding returns, but in general:

- If you are fully (or nearly fully) **breast-feeding**, [RH106 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**, [RH106 trade name] can be started 6 weeks after the birth of your baby
- If you are **not breast-feeding**, [RH106 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 [RH106 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.

[RH106 trade name] 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 [RH106 trade name] 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 [RH106 trade name] and which type of contraception you should use in the meantime.

### **4. Possible side effects**

Like all medicines, [RH106 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 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**

[RH106 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 [RH106 trade name], 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 [RH106 trade name], 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 [RH106 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 [RH106 trade name]**

Do not store above 30°C. Do not refrigerate or freeze.  
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 [RH106 trade name] contains**

- The active ingredient is Medroxyprogesterone acetate.
- The other ingredients of [RH106 trade name] are polyethylene glycol 3350, polysorbate 80, sodium chloride, methyl paraben, propyl paraben, povidone, L-methionine, disodium hydrogen phosphate dodecahydrate, sodium dihydrogen phosphate monohydrate, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment), 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 [RH106 trade name] looks like and contents of the pack**

[RH106 trade name] is a white to off-white sterile suspension for injection.

[RH106 trade name] is supplied in a single-dose pre-filled injection injector called uniject.

Each uniject injector comprises a linear plastic (low-density polyethylene laminate) reservoir with a siliconized stainless steel needle attached via a plastic (low-density polyethylene) port and valve. Each uniject injector is enclosed in an aluminium foil pouch. Each pouch or one hundred individually pouched uniject injectors are packed in a printed unit carton.

## Instructions for use

### *Learning to inject [RH106 trade name]*

Your health care provider will start regular injections of [RH106 trade name]. If it is right for you, the health care provider will teach you how to inject [RH106 trade name] yourself. You will need to learn about:

- the injection schedule—so you inject [RH106 trade name] regularly on the right dates
- where to inject [RH106 trade name]
- preparing and injecting [RH106 trade name]

Even if you give the injection yourself, plan to see your health care provider regularly and at least once a year. In this way, your health care provider can check that [RH106 trade name] is working well.

### *Injection schedule*

To make sure you get your injections on time every 13 weeks, put a reminder of the next injection dates on a calendar, diary or on your phone.

For detailed information see the separate section at the end of this information leaflet.

If you have any questions on the use of this medicine, ask your health care provider, particularly if there have been any problems during or immediately after the injection.

## Supplier and Manufacturer

### *Supplier*

Incepta Pharmaceuticals Ltd  
40 Shahid Tajuddin Ahmed Sarani,  
Tejgaon I/A,  
Dhaka-1208  
Bangladesh  
Email: [enquiry@inceptapharma.com](mailto:enquiry@inceptapharma.com)

### *Manufacturer*

Incepta Pharmaceuticals Ltd  
Unit-10, Injectable Potent Drug (IPD),  
Krishnapura, Sahabelishor  
Dhamrai, Dhaka  
Bangladesh  
Tel: +880222-4498137  
Fax: +880222-4498135  
Email: [enquiry@inceptapharma.com](mailto:enquiry@inceptapharma.com)

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

**This leaflet was last revised in March 2026**

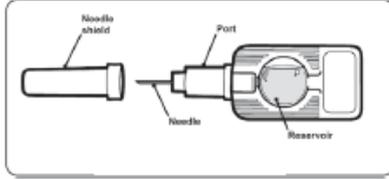
*Detailed information on this medicine is available on the World Health Organization (WHO) website:*  
<https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>

**INSTRUCTIONS FOR USE**

[RH106 trade name] 104 mg/0.65 ml Suspension for Injection Single-dose container Medroxyprogesterone acetate

**For Subcutaneous Injection Only**

[RH106 trade name] can be given by a health care provider or by the patient.



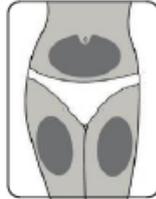
**Gather your supplies**

- Gather the following supplies on a clean flat surface:
- A [RH106 trade name] injector (in its sealed foil pouch).
  - A suitable container for the used injector.
  - A clean cotton pad or clean paper tissue.



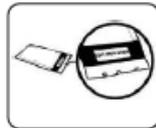
**Step 1: Select and clean injection area**

- Wash and dry your hands thoroughly before starting.
- Choose a suitable area for the injection, either the abdomen (belly) or the front upper thigh.
  - Do not inject into bony areas or close to the navel (belly button).
  - Do not inject into skin that is scarred or where there are skin conditions such as eczema or psoriasis.
  - Change the injection site for each new injection.
  - Clean the area of skin as instructed by your health care provider.



**Step 2: Prepare for use**

- Check that the pouch is not open or does not appear to be damaged.
  - Check that the expiry date has not passed.
- Ensure that the pouch is at room temperature below 30 °C.

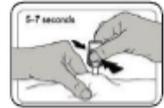


**Step 8: Inject the dose**

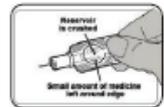
- Gently pinch a large area of skin with one hand. Keep the skin pinched all through this step.
- With the other hand, hold the injector by the port with the needle pointing downwards.



- Insert the needle into the skin until the port just touches the skin.
- Squeeze the reservoir slowly to inject the medicine. You should take about 5-7 seconds to do this.
- Gently pull the needle out of the skin. Let go of the skin.
- Check whether the medicine has leaked out of the injector or has appeared on the skin. If so, a problem has occurred. (Please refer to information overleaf).

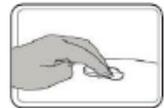


- After the injection, a small amount of medicine will be left around the inside edge of the reservoir. This is normal.
- If you believe for any reason that the full dose has not been given, speak to your health care provider about alternative methods of contraception until the next scheduled injection.



- Do not inject a second dose.

- Use a clean cotton pad to press lightly on the injection area for a few seconds



- Do not rub the area.

**Step 9: Dispose of the injector**

The injector is for single use only. Do not reuse the injector. Dispose of the used injector in a suitable container as advised by your health care provider.



**After injection care**

- Monitor the appearance of the injection site until the next injection.
- If you notice any skin indentation or dimpling at the injection site tell your health care provider.
- If you experience any symptoms of allergic reaction (see leaflet Section 4 overleaf), seek medical help immediately.

**Record the date**

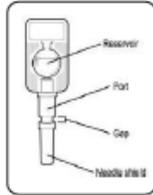
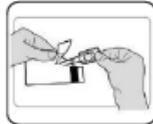
Record the date of your injection and should you wish to continue, calculate the date of your next scheduled injection of [RH106 trade name].

**Reminder for next injection:** To make sure you get your injections on time every 13 weeks, put a reminder of the next injection dates on a calendar, diary or on your phone.

Date  
 Date of next injection (add 3 months)

**Step 3: Remove injector from pouch**

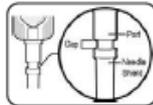
- Carefully tear open the foil pouch at the tear notch.
  - Take out the injector.
- Do not remove the needle shield from the injector yet.



**Step 4: Check the injector**

Check the injector. There should be a gap between the needle shield and the port. Discard the injector and use a new one if:

- there is no gap
- the injector is damaged
- the needle shield has come off, or is missing



**Step 5: Mix the medicine and Check the medicine**

- Hold the injector firmly by the port.
- Shake the injector vigorously for at least 30 seconds to mix the medicine.

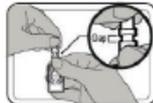


- After shaking, check the medicine in the reservoir. It should appear evenly white.
    - Discard the injector and use a new one if:
      - the medicine is not white and uniform
      - the medicine is leaking
- If there is any delay before injecting, you must repeat the mixing step.

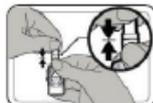


**Step 6: Activate the injector**

- Hold the injector firmly by the port with one hand.
- Make sure the needle shield is pointing upwards.
- Do not squeeze the reservoir.



- Hold the needle shield with the other hand.
- Push the needle shield firmly towards the port until it will go no further.



- Confirm there is no gap remaining. This means you have activated the injector correctly.

