WHO-PQ RECOMMENDED SUMMARY OF PRODUCT CHARACTERISTICS

This summary of product characteristics 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

1. NAME OF THE MEDICINAL PRODUCT

[RH106 trade name]†

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.65mL contains 104mg of medroxyprogesterone acetate

Excipients with potential clinical effect

Each 0.65mL contains

- Methyl paraben, 1.04mg
- Propyl paraben, 0.098mg

3. PHARMACEUTICAL FORM

Sterile suspension for injection.

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

White to off-white sterile suspension for injection

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[RH106 trade name] is used for long-term contraception in women. Each injection provides contraception for at least 12 weeks. However, it should be taken into consideration that the return to fertility (ovulation) may be delayed for up to one year (see section 4.4).

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

- the woman's male partner is awaiting vasectomy to become effective;
- the woman is awaiting sterilisation;
- the woman at risk of rubella is awaiting immunisation against rubella.

4.2 Posology and method of administration

Posology

[RH106 trade name] is presented as a single-dose container with 104 mg medroxyprogesterone acetate. It is administered once every 13 weeks (3 months).

Starting [RH106 trade name]

The first dose of [RH106 trade name] can be given:

- within 7 days of the start of the woman's monthly bleeding
- immediately if switching from an intra-uterine device (IUD)
- immediately if switching from a correctly used hormonal method
- immediately if switching when a repeat injection of another injectable method is due

If more than 7 days have passed since the start of her monthly bleeding, or the woman does not have monthly bleeding, or the woman has not been using another contraception method consistently, she can receive the

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

injection at any time if it is reasonably certain she is not pregnant. In such a case she should use an additional (backup) method of contraception for the first 7 days.

After birth

Fully or nearly fully breast-feeding

The first dose of [RH106 trade name] can be given:

- any time between 6 weeks and 6 months of birth if the woman's monthly bleeding has not returned and it is reasonably certain she is not pregnant
- any time after more than 6 months of birth if the woman's monthly bleeding has not returned and it is reasonably certain she is not pregnant; an additional (backup) method of contraception should be used for the first 7 days
- if the woman's monthly bleeding has returned, within 7 days of the start of monthly bleeding

Partially breast-feeding

The first dose of [RH106 trade name] can be given:

- 6 weeks after birth
- any time after more than 6 weeks of birth if the woman's monthly bleeding has not returned and it is reasonably certain she is not pregnant; an additional (backup) method of contraception should be used for the first 7 days
- if the woman's monthly bleeding has returned, within 7 days of the start of monthly bleeding

Not breast-feeding

The first dose of [RH106 trade name] can be given:

- any time within 4 weeks of birth
- any time after 4 weeks of birth the woman's monthly bleeding has not returned and it is reasonably certain she is not pregnant; an additional (backup) method of contraception should be used for the first 7 days
- if the woman's monthly bleeding has returned, within 7 days of the start of monthly bleeding

After miscarriage or abortion

The first dose of [RH106 trade name] can be given:

- within 7 days of first- or second-trimester miscarriage or abortion
- any time after 7 days of first- or second-trimester miscarriage or abortion if it is reasonably certain the woman is not pregnant; an additional (backup) method of contraception should be used for the first 7 days

After progesterone-containing emergency contraceptive pill

[RH106 trade name] can be started or restarted:

- on the same days as taking the progesterone emergency contraceptive pill; an additional (backup) method of contraception should be used for the first 7 days
- any time after taking the emergency contraceptive pill if it is reasonably certain the woman is not pregnant

After ulipristal acetate emergency contraceptive pill

[RH106 trade name] can be started or restarted:

- 6 days after taking the ulipristal acetate emergency contraceptive pill (contraceptive effectiveness may be reduced if [RH106 trade name] is given earlier than 6 days after using ulipristal acetate); an additional (backup) method of contraception should be used for the first 7 days after the injection
- any time if more than 6 days have passed after taking the emergency contraceptive pill and it is reasonably certain the woman is not pregnant

Managing late injections

If [RH106 trade name] is given within 4 weeks of the due dose, the woman can receive her next injection. There is no need for tests, evaluation or a backup method.

If the dose [RH106 trade name] is more than 4 weeks late, the woman can receive her next injection if:

- she has not had sex since 2 weeks after the scheduled date of her injection, or
- she has used a backup method or has taken emergency contraceptive pills after any unprotected sex since 2 weeks after the scheduled date of her injection, or
- she is fully or nearly fully breast-feeding and gave birth less than 6 months ago.

If [RH106 trade name] is given more than 4 weeks late, the woman will need to abstain from sex or use a backup method for the first 7 days after receiving [RH106 trade name].

Hepatic impairment

The effect of hepatic disease on the pharmacokinetics of [RH106 trade name] is unknown. As medroxyprogesterone largely undergoes hepatic elimination it may be poorly metabolised in patients with severe hepatic insufficiency (see section 4.3).

Renal impairment

The effect of renal disease on the pharmacokinetics of [RH106 trade name] is unknown. No dosage adjustment should be necessary in women with renal insufficiency, since medroxyprogesterone is almost exclusively eliminated by hepatic metabolism.

Paediatric population

[RH106 trade name] is not indicated before menarche. Other than concerns about loss of bone mineral density, the safety and effectiveness of [RH106 trade name] is expected to be the same for adolescents after menarche and adult females.

Method of administration

Administration of [RH106 trade name] should be initiated under the supervision of a health care provider. After proper training in injection technique and schedule of administration, women may self-inject [RH106 trade name] so long as referral links to a health care provider are strong, and women who self-inject are monitored and followed up.

[RH106 trade name] is administered by **subcutaneous** injection into the back of the arm or the abdomen or the front of the thigh, according to the woman's preference. The injection is prepared and given as follows:

- The [RH106 trade name] single-dose container should be at room temperature.
- Wash and dry hands properly before handling the injection. Clean the injection site.
- Hold the device by the port (not the cap), taking care not to squeeze the reservoir. Shake the device hard for 30 seconds to ensure the suspension is completely uniform.
- Point the needle upward.
- Hold the cap with one hand and the port with the other hand. Press the cap down firmly down to the port to remove it.
- Gently pinch the skin at the injection site and push the needle downwards into the skin until the port touches the skin completely.
- Squeeze the reservoir slowly over 5 to 7 seconds to inject the full dose subcutaneously.
- Pull out the needle and release the skin. Do not massage the site after injection.

4.3 Contraindications

[RH106 trade name] must not be used if the woman:

- has hypersensitivity to medroxyprogesterone acetate or to any of the excipients listed in section 6.1
- has or has had breast cancer
- has unexplained vaginal bleeding
- has severe hepatic disease
- has vascular disease
- has acute deep vein thrombosis or pulmonary oedema
- has or has had ischaemic heart disease or stroke
- has significant hypertension (systolic pressure of 160 mmHg or higher, diastolic pressure of 100 mmHg or higher)
- has had diabetes for longer than 20 years or has complications of the disease (circulatory, renal, nervous or ophthalmic)
- has a combination of risk factors (e.g. hypertension, diabetes) for cerebrovascular disease
- has systemic lupus erythematosus with positive test for antiphospholipid antibodies or severe thrombocytopenia
- has meningioma or history of meningioma.

4.4 Special warnings and precautions for use

Personal and family medical history should be assessed before starting hormonal contraceptives (and at regular intervals afterwards). The frequency and nature of the assessment should be adapted to the individual woman. It should include measurement of blood pressure and, if appropriate, breast, abdominal and pelvic examination including cervical cytology.

Loss of bone mineral density

During use, depot medroxyprogesterone acetate decreases bone mineral density slightly. This may increase the risk of developing osteoporosis and possibly also increase the risk of bone fractures later, after menopause. However, this decrease in bone density does not place age or time limits on the use of depot medroxyprogesterone acetate injection.

The risk of osteoporosis can also be increased by lifestyle or medical risk factors. Important risk factors for osteoporosis include:

• Alcohol abuse or tobacco use

• Prolonged use of medicines that can reduce bone mass, e.g. anticonvulsants or corticosteroids

• Low body mass index or eating disorder, e.g. anorexia nervosa or bulimia

• Previous low trauma fracture

• Family history of osteoporosis

Adequate intake of calcium and Vitamin D, whether from the diet or from supplements, is important for bone health in women of all ages.

Menstrual irregularity

Menstrual bleeding pattern is altered in most women using subcutaneous injection of depot medroxyprogesterone acetate. They should be counselled about the likelihood of menstrual disturbance and possible delay in return to ovulation.

With continued use, fewer women have irregular bleeding, and more women have no monthly bleeding. In addition to amenorrhea, altered bleeding patterns can include intermenstrual bleeding and heavy or prolonged bleeding. If abnormal bleeding persists or is severe, the woman may need investigation and treatment.

Return to fertility

Pregnancies have occurred as early as 14 weeks after an injection of depot medroxyprogesterone acetate. However, on average, women become pregnant 10 months after their last injection. Women should be counselled of possible delay in return to full fertility, regardless of the duration of use but over 80 % of women may be expected to conceive within 15 months of the last injection.

Protection against sexually transmitted infections

Women should be counselled that [RH106 trade name] does not protect against sexually transmitted infections including HIV infection (AIDS). Safer sex practices including correct and consistent use of condoms reduce the transmission of infections through sexual contact.

Cancer risk

Depot medroxyprogesterone acetate does not cause cancer. Long-term case-controlled surveillance of women using depot medroxyprogesterone acetate by the intramuscular route found no overall increased risk of ovarian, liver, or cervical cancer and a prolonged, protective effect of reducing the risk of endometrial cancer in the population of users.

Findings of the few studies on DPMA use and breast cancer are similar to findings with combined oral contraceptives: women using depot medroxyprogesterone acetate were more likely to be diagnosed with breast cancer while using it or within 10 years after stopping. It is unclear whether these findings are explained by earlier detection of existing breast cancers among users of depot medroxyprogesterone acetate or by its biological effect on breast cancer.

The risk of cervical cancer may be slightly increased among women using depot medroxyprogesterone acetate for 5 years or more. Cervical cancer cannot develop because of depot medroxyprogesterone acetate alone; it is caused by persistent infection with human papillomavirus.

Meningioma

Cases of meningioma (single and multiple) have been reported in those receiving medroxyprogesterone acetate over several years. Women receiving medroxyprogesterone acetate should be monitored for signs and symptoms of meningioma.

In some cases, the meningioma shrank after discontinuing depot medroxyprogesterone acetate. If a woman is diagnosed with meningioma, medroxyprogesterone acetate must be stopped, as a precaution.

Weight gain

Women gain an average of 1–2 kg per year when using depot medroxyprogesterone acetate injection. Some of this gain may be the usual increase in weight as people age. Some women, particularly overweight adolescents, have gained much more than 1–2 kg per year.

However, some users of progestogen-only injections may either lose weight or their weight may not change significantly.

Fluid retention

Women with illnesses including epilepsy, migraine, asthma, heart failure, or renal dysfunction should be closely watched because use of progestogens, such as medroxyprogesterone acetate, may result in some fluid retention.

Hypertension and lipid disorders

Limited evidence suggests a slightly higher risk of cardiovascular events among women with hypertension or with lipid disorders who used progestogen-only injectables. If hypertension occurs under [RH106 trade name] treatment and it cannot be adequately controlled by antihypertensive medicines, treatment with [RH106 trade name] should be stopped.

Risk factors for arterial thrombotic disorders include hypertension, smoking, age, lipid disorders, migraine, obesity, family history of arterial thrombosis, cardiac valve disorders, and atrial fibrillation. [RH106 trade name] should be used cautiously in patients with one or more of these risk factors.

Thromboembolic disorders

If the woman receiving depot medroxyprogesterone acetate develops pulmonary embolism, cerebrovascular disease or retinal thrombosis, it should not be given again.

Psychiatric disorders

Those with a history of endogenous depression should be carefully monitored. Some women may complain of premenstrual-type depression while receiving depot medroxyprogesterone acetate.

Depressed mood and depression are well-known undesirable effects of hormonal contraceptives. Depression can be serious and may lead to suicidal behaviour and suicide. Women should be advised to contact their health care provider about mood changes and depressive symptoms, including those that occur shortly after starting contraception.

Abscess formation

As with any subcutaneous injection, especially if not administered correctly, there is a risk of abscess formation at the site of injection, which may require medical or surgical intervention.

Precautions

History or emergence of the following conditions require careful consideration and appropriate investigation: migraine or unusually severe headaches, acute visual disturbances of any kind, pathological changes in liver function and hormone levels.

Those with thromboembolic or coronary vascular disease should be carefully evaluated before using depot medroxyprogesterone acetate.

Glucose tolerance may decrease in some women receiving progestogens. Women with diabetes should be carefully monitored while receiving [RH106 trade name].

Laboratory tests

Health care providers should inform pathologists of the use of [RH106 trade name] if endometrial or endocervical tissue is submitted for examination.

The results of certain laboratory tests may be affected by the use of [RH106 trade name]. These include gonadotrophin levels (decreased), plasma progesterone levels (decreased), urinary pregnanediol levels (decreased), plasma oestrogen levels (decreased), plasma cortisol levels (decreased), glucose tolerance test, metyrapone test, liver function tests (may increase), thyroid function tests (protein-bound iodine levels may increase and T3 uptake levels may decrease). Coagulation test values for prothrombin (Factor II), and Factors VII, VIII, IX and X may increase.

It is important to consider the contribution of excipients from all the medicines that the patient is taking.

4.5 Interaction with other medicinal products and other forms of interaction

The bioavailability of medroxyprogesterone acetate may be significantly reduced when it is co-administered with aminoglutethimide.

Interactions with medicines (including oral anticoagulants) have been reported rarely, and causality has not been determined. The possibility of interaction should be borne in mind in patients receiving concurrent treatment with other drugs.

Medroxyprogesterone acetate is metabolised in vitro primarily by hydroxylation via CYP3A4. However, the clearance of medroxyprogesterone acetate is about equal to the rate of hepatic blood flow. It is therefore unlikely that inducers of hepatic enzymes will significantly affect the kinetics of medroxyprogesterone acetate. [RH106 trade name] may be used by women who take the following CYP3A4 inducers:

carbamazepine, efavirenz, fosphenytoin, nevirapine, oxcarbazepine, phenobarbital, phenytoin, primidone, rifabutin, rifampicin, and St John's wort (*Hypericum perforatum*).

4.6 Fertility, pregnancy and breastfeeding

Pregnancy
Depot medroxyprogesterone acetate will not cause birth defects and will not otherwise harm the fetus if a woman becomes pregnant while using progestogen-only injection or accidentally starts injections when she is pregnant.

Children exposed to medroxyprogesterone acetate in utero and followed to adolescence showed no evidence of any adverse effect on their health including their physical, intellectual, sexual or social development.

Breast-feeding
Medroxyprogesterone acetate is present in breast milk in small amounts. Depot medroxyprogesterone acetate is not likely to affect either the breast-feeding mother or the baby.

[RH106 trade name] can be used during breast-feeding, starting as early as 6 weeks after birth. It does not affect milk production.

Fertility
Return to fertility (conception) may be delayed following discontinuation of [RH106 trade name] (see section 4.4). The bleeding pattern a woman had before she used depot medroxyprogesterone acetate generally returns several months after the last injection even if she had no monthly bleeding while using [RH106 trade name].

4.7 Effects on ability to drive and use machines

[RH106 trade name] is unlikely to affect the ability to drive or operate machinery.

However, patients should be advised to consider if their clinical status, including any undesirable effects of the medicine, allows them to perform skilled tasks safely.

4.8 Undesirable effects

Tabulated list of adverse reactions

Those most frequently (more than 5%) reported adverse drug reactions were headache (8.9%), metrorrhagia (7.1%), weight increased (6.9%), amenorrhoea (6.3%) and injection site reactions (any type, 6.1%).

Adverse reactions to [RH106 trade name] are listed below by body system or organ. Frequencies are defined as follows: very common (at least 1 in 10), common (1 in 100 to 1 in 10) uncommon (1 in 1000 to 1 in 100), rare (1 in 10 000 to 1 in 1000), very rare (less than 1 in 10 000) or frequency not known (frequency cannot be estimated from available data).

Neoplasms benign, malignant and unspecified	
Rare	breast cancer
Frequency not known	cervical cancer (see section 4.4), meningioma
Blood and lymphatic system disorders	
Rare	anaemia, blood disorder
Immune system disorders	
Uncommon	drug hypersensitivity
Rare	anaphylactic reaction, anaphylactoid reaction, angioedema
Metabolism and nutrition disorders	
Uncommon	increased appetite, decreased appetite

Psychiatric disorders

Common	depression, decreased libido, insomnia, anxiety, affective disorder, irritability
Uncommon	nervousness, emotional disorder, anorgasmia

Nervous system disorders

Common	dizziness, headache
Uncommon	migraine, somnolence, paraesthesia
Rare	syncope
Frequency not known	seizure

Ear and labyrinth disorders

Uncommon	vertigo

Cardiac disorders

Uncommon	tachycardia

Vascular disorders

Uncommon	hypertension (see section 4.4), varicose vein, hot flush
Frequency not known	embolism and thrombosis, deep vein thrombosis, thrombophlebitis

Respiratory, thoracic and mediastinal disorders

Uncommon	dyspnoea
Rare	pulmonary embolism
Frequency not known	asthma, hoarseness

Gastrointestinal disorders

Common	abdominal pain, nausea
Uncommon	abdominal distension
Rare	rectal haemorrhage

Hepatobiliary disorders

Uncommon	abnormal hepatic function
Rare	jaundice, hepatic enzyme abnormalities

Skin and subcutaneous tissue disorders

Common	acne
Uncommon	alopecia, hirsutism, urticaria, pruritus, chloasma, rash, ecchymosis, dermatitis
Rare	lipodystrophy, scleroderma
Frequency not known	skin striae

Musculoskeletal and connective tissue disorders

Common	back pain, pain in extremity
Uncommon	arthralgia, muscle spasms
Frequency not known	osteoporosis, osteoporotic fractures

Reproductive system and breast disorders

Common	metrorrhagia, menometrorrhagia, menorrhagia, dysmenorrhea, amenorrhea, vaginitis, breast tenderness, genitourinary tract infection
Uncommon	ovarian cyst, uterine bleeding (irregular, increased, decreased, spotting), vaginal discharge, galactorrhoea, pelvic pain, vulvovaginal dryness, premenstrual syndrome, breast enlargement, dyspareunia, suppressed lactation
Rare	breast atrophy, endometrial hyperplasia, breast mass, bloody exudate from nipples, vaginal cyst, lack of return to fertility, sensation of pregnancy

General disorders and administration site conditions

Common	fatigue, injection site reaction, injection site persistent atrophy/indentation/dimpling at injection site, injection site nodule/lump, injection site pain/tenderness
Uncommon	Pyrexia, fluid retention
Rare	thirst, dysphonia, facial nerve paralysis, axillary swelling, asthenia, injection site discoloration
Frequency not known	Chills

Investigations

Common	weight increased, abnormal cervical smear
Uncommon	Bone density decreased (see section 4.4); glucose tolerance decreased (see section 4.4); abnormal hepatic enzyme
Rare	weight decreased

Reporting of suspected adverse reactions

Health care providers are asked to report adverse reactions that may be linked to a medicine, to the marketing authorisation holder, or, if available, to the national reporting system. Reports of suspected adverse reactions to a medicine are important for the monitoring of the medicine's benefits and risks.

4.9 Overdose

Overdose is unlikely with an injection of depot medroxyprogesterone acetate. However, if excessive amount is injected, no immediate action is necessary. Consideration may need to be given to delaying subsequent injection.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Progestogens, ATC code: G03AC06

Medroxyprogesterone acetate exerts anti-oestrogenic, anti-androgenic and anti-gonadotrophic effects.

Mechanism of action

Depot medroxyprogesterone acetate, administered parenterally at the recommended dose to women, inhibits the secretion of gonadotropins, which prevents follicular maturation and ovulation and causes thickening of cervical mucus that inhibits sperm entry into the uterus.

Meningioma

Based on a French epidemiological case-control study, there may be an association between medroxyprogesterone acetate and meningioma. This study included 18 061 women who had intracranial surgery for meningioma and 90 305 women without meningioma. Use of medroxyprogesterone acetate

150 mg/3 mL injection was compared between women who had intracranial surgery for meningioma and women without meningioma. An excess risk of meningioma was found with the use of medroxyprogesterone acetate 150 mg/3 mL (9/18 061 [0.05%] vs 11/90 305 [0.01%], OR 5.55 [95% CI 2.27 to 13.56]). This excess risk seems to be driven primarily by prolonged use (3 years or more) of medroxyprogesterone acetate.

5.2 Pharmacokinetic properties

Absorption of [RH106 trade name] The absorption characteristics of [RH106 trade name] have been determined after administration of one (1) intramuscular injection in healthy adult female volunteers in the fasting state as follows:

Pharmacokinetic variable	**Arithmetic mean ± SD (*)**
	Medroxyprogesterone acetate
Maximum concentration (C_{max}) ng/mL	1.178 ± 0.422 (1.111)
$AUC_{0\text{-}91d}$ (ng.h/ml)	1154 ± 367 (1095)
$AUC_{0\text{-}140d}$ (ng.h/ml)	1486 ± 452 (1413)
Time to attain maximum concentration (T_{max}) hour	144 ± 203

*geometric mean

Pharmacokinetics of medroxyprogesterone acetate

General	
	Medroxyprogesterone acetate (as a depot formulation) has a long duration of action as a result of slow absorption from the injection site.
Absorption	
Oral bioavailability	Not applicable
Distribution	
Volume of distribution (mean)	NA*
Plasma protein binding	86 %
Tissue distribution	Medroxyprogesterone acetate binding occurs primarily to serum albumin. It crosses the blood-brain barrier and is present in breast milk.
Metabolism	
	The principal metabolite is 6α-methyl-6β, 17α, 21-trihydroxy-4-pregnene-3, 20-dione-17-acetate. At least 11 metabolites have been reported. All are excreted in the urine, some, but not all, conjugated. CYP3A4 is involved in the metabolism.
Active metabolite	None
Elimination	
Elimination half-life	About 40 days (following subcutaneous injection)
Mean systemic clearance (Cl/F)	NA*
% of dose excreted in urine	NA*
% of dose excreted in faeces	NA*
Metabolizing enzymes	CYP3A4

NA* Not available

Patients with hepatic impairment

The effect of a hepatic impairment on the pharmacokinetics of medroxyprogesterone acetate is unknown. However, medroxyprogesterone acetate is almost exclusively eliminated by hepatic metabolism and metabolism may be reduced in patients with hepatic impairment.

Patients with renal impairment.

The effect of renal impairment on the pharmacokinetics of medroxyprogesterone acetate is unknown.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential.

Medroxyprogestrone acetate has adverse effects on reproduction in animal studies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl paraben
Propyl paraben
Sodium chloride
Polyethylene glycol 3350
Polysorbate 80
Povidone
L-methionine
Disodium hydrogen phosphate dodecahydrate
Sodium dihydrogen phosphate monohydrate
Sodium hydroxide (for adjustment of pH)
Hydrochloric acid (for adjustment of pH)
Water for injection

This medicine is essentially ‘sodium-free’. It contains less than 1 mmol sodium (23 mg) per prefilled syringe

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30ºC. Do not refrigerate or freeze. Nature and contents of container

[RH106 trade name] is supplied in a single-dose pre-filled injection injector called uniject. Each uniject injector comprises a linear low-density polyethylene laminate reservoir with a siliconized stainless steel, thin wall needle attached via a 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.

6.5 Special precautions for disposal and other handling

For single use only. Once opened: use immediately, discard any unused portion

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

7. SUPPLIER

Incepta Pharmaceuticals Ltd
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8. WHO REFERENCE NUMBER (WHO Prequalification Programme)

RH106

9. DATE OF PREQUALIFICATION

01 October 2025

10. DATE OF REVISION OF THE TEXT

March 2026

References

World Health Organization Department of Sexual and Reproductive Health and Research and Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs, Knowledge SUCCESS. Family planning: a global handbook for providers (2022 update). Baltimore and Geneva: CCP and WHO; 2022. (https://fphandbook.org/sites/default/files/WHO-JHU-FPHandbook-2022Ed-v221115a.pdf, accessed 17 July 2025)

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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