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

[RH084 trade name]†

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of suspension contains 150 mg medroxyprogesterone acetate

Excipients with potential clinical effect

Each mL contains

- Methyl paraben 1.37 mg
- Propyl paraben 0.15 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Sterile Suspension for injection

White to off-white sterile suspension for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[RH084 trade name] is used for contraception in women. Each injection provides contraception for at least 12 weeks.

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

[RH084 trade name] is given intramuscularly every 12 weeks.

Starting [RH084 trade name]

The first dose of [RH084 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 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 [RH084 trade name] can be given:

- any time between 6 weeks and 6 months of birth if the woman's monthly bleeding has not returned

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

- 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 [RH084 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 [RH084 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 [RH084 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

[RH084 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

[RH084 trade name] can be started or restarted:

- 6 days after taking the ulipristal acetate emergency contraceptive pill (contraceptive effectiveness may be reduced if [RH084 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 [RH084 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 [RH084 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 [RH084 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 [RH084 trade name].

Method of administration

[RH084 trade name] is given by intramuscular injection into the ventro-gluteal muscle, or into the deltoid muscle, or into the upper outer aspect of the gluteal muscle. The site is chosen according to the woman's preference.

4.3 Contraindications

[RH084 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 hormone-dependent malignancy of breast or genital organs
- has undiagnosed abnormal uterine bleeding
- has a history of severe hepatic disease and liver function tests have not returned to normal
- 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 or has had ischemic heart disease (e.g. myocardial infarction) or stroke
- has or has had arterial thrombosis
- has acute deep vein thrombosis or pulmonary embolism
- 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

The use of medroxyprogesterone acetate reduces serum oestrogen levels and is associated with significant loss of bone mineral density (BMD) due to the known effect of oestrogen deficiency on the bone remodelling system. Bone loss is greater with long-term use of medroxyprogesterone acetate; however, BMD appears to increase after medroxyprogesterone acetate is discontinued and ovarian oestrogen production increases.

This loss of BMD is of particular concern during adolescence and early adulthood, a critical period of bone growth. It is unknown if use of medroxyprogesterone acetate by younger women will reduce peak bone mass and increase the risk for fracture in later life.

WHO has concluded that the decrease in bone mineral density does not place age or time limits on use of medroxyprogesterone acetate.

A study to assess the BMD effects of medroxyprogesterone acetate-IM in adolescent females showed a decrease in BMD from baseline. In the small number of women who were followed-up, mean BMD recovered to around baseline values by 1- 3 years after discontinuing treatment. In adolescents, medroxyprogesterone acetate may be used, but only after other methods of contraception have been discussed with the patients and considered to be unsuitable or unacceptable.

In women of all ages, careful re-evaluation of the risks and benefits of treatment should be carried out in those who wish to continue use for more than 2 years.

In particular, in women with significant lifestyle or medical risk factors for osteoporosis, other methods of contraception should be considered prior to use of medroxyprogesterone acetate.

Significant risk factors for osteoporosis include:

• Alcohol abuse or tobacco use
• Chronic use of drugs 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

A retrospective cohort study reported that women using medroxyprogesterone acetate injections (DMPA), have a higher risk of fracture compared with contraceptive users with no recorded use of DMPA (incident rate ratio 1.41, 95% CI 1.35-1.47 for the five year follow-up period); it is not known if this is due to DMPA, or to other related lifestyle factors which have a bearing on fracture rate. By contrast, in women using DMPA, the fracture risk before and after starting DMPA was not increased (relative risk 1.08, 95% CI 0.92-1.26). Importantly, this study could not determine whether use of DMPA has an effect on fracture rate later in life.

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

Depot medroxyprogesterone acetate usually disrupts the normal menstrual cycle. Bleeding patterns include amenorrhoea (in up to 30% of women during the first 3 months, increasing to 55% by month 12 and 68% by month 24); irregular bleeding and spotting; prolonged (longer than 10 days) episodes of bleeding (up to 33% of women in the first 3 months of use decreasing to 12% by month 12).

Prolonged or heavy bleeding requiring treatment may occur in 0.5–4 occasions per 100 woman-years of use. Persistent or severe abnormal bleeding should be investigated to rule out organic pathology and treatment started if necessary. Excessive or prolonged bleeding can be controlled using oestrogen either as a low-dose (30 micrograms oestrogen) combined oral contraceptive pill or as oestrogen-replacement therapy such as conjugated equine oestrogen (0.625–1.25 mg daily). Oestrogen therapy may need to be repeated for 1–2 cycles. Long-term use of oestrogen is not recommended.

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.

HIV acquisition risk

[RH084 trade name] does not protect against HIV acquisition. Where HIV is common, health care providers should inform women considering a progestogen-only injection how to protect themselves from HIV, so that each woman can make a fully informed choice.

Cancer risk

Depot medroxyprogesterone acetate does not cause cancer. It helps protect against cancer of the lining of the uterus (endometrial cancer). Findings of the few studies on its 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 may gain weight while receiving depot medroxyprogesterone acetate. Studies indicate that over the first 1–2 years of use, the average weight gain was 2–4 kg. Women completing 4–6 years of depot medroxyprogesterone acetate contraception gained on average 6–7.5 kg. The weight gain is accounted by increased fat and is not secondary to an anabolic effect or fluid retention. Some of the increase in weight may be the usual weight that people gain as they age.

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.

Anaphylaxis

Reactions such as anaphylaxis, anaphylactic shock and anaphylactoid reactions have been reported in individuals receiving medroxyprogesterone acetate.

Lipids

No clear impact of medroxyprogesterone acetate on lipid metabolism has been demonstrated. Both increases and decreases in total cholesterol, triglycerides and low-density lipoprotein (LDL) cholesterol have occurred.

Depot medroxyprogesterone acetate appears to be associated with a 15–20% reduction in serum high-density lipoprotein (HDL) cholesterol levels which may protect women from cardiovascular disease. The clinical consequences of this observation are unknown. The potential for an increased risk of coronary disease should be considered before use.

Thromboembolic disorders

If the woman receiving depot medroxyprogesterone acetate develops pulmonary embolism, cerebrovascular disease or retinal thrombosis, it should not be given again. There have been rare cases of thromboembolism with use of depot medroxyprogesterone acetate, but causality has not been established.

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 intramuscular 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 individuals receiving progestogens. Women with diabetes should therefore be carefully monitored while receiving [RH084 trade name].

Health care providers should carefully consider the use of depot medroxyprogesterone acetate in those with recent trophoblastic disease before levels of human chorionic gonadotrophin have returned to normal.

Health care providers should inform pathologists of the use of [RH084 trade name] if endometrial or endocervical tissue is submitted for examination.

The results of certain laboratory tests may be affected by the use of [RH084 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.

Women should be counselled that [RH084 trade name] does not protect against sexually transmitted infections (STIs) including HIV infection (AIDS). Safer sex practices including correct and consistent use of condoms reduce the transmission of STIs through sexual contact.

The benefits of contraceptive options and their risks must be evaluated individually for each woman.

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. [RH084 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 breast-feeding

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.

[RH084 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 [RH084 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 [RH084 trade name].

4.7 Effects on ability to drive and use machines

[RH084 trade name] may cause headaches and dizziness. Patients should be advised not to drive or operate machinery if affected.is unlikely to affect the ability to drive or operate machinery.

4.8 Undesirable effects

Tabulated list of adverse reactions

Those most frequently (more than 5%) reported adverse drug reactions were weight gain (69%), menstrual irregularities (57% in first 12 months), weight loss (25%), headache (16%), nervousness (11%), abdominal pain or discomfort (11%), dizziness (6%), and decrease in libido (6%).

Adverse reactions to [RH084 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	
Very common	nervousness
Common	depression, libido decreased
Uncommon	insomnia
Rare	anorgasmia, emotional disturbance, affective disorder, irritability, anxiety
Nervous system disorders	
Very common	headache
Common	dizziness
Uncommon	seizure, somnolence, paraesthesia
Rare	migraine, paralysis, syncope
Ear and labyrinth disorders	
Rare	vertigo
Cardiac disorders	
Rare	tachycardia
Vascular disorders	
Uncommon	hot flush
Rare	embolism and thrombosis, deep vein thrombosis, thrombophlebitis, hypertension, varicose veins

Respiratory, thoracic and mediastinal disorders

Uncommon	dyspnoea
Rare	pulmonary embolism
Frequency not known	asthma, hoarseness

Gastrointestinal disorders

Very common	abdominal pain, abdominal discomfort
Common	nausea, abdominal distension
Rare	rectal haemorrhage

Hepatobiliary disorders

Uncommon	abnormal hepatic function
Rare	jaundice, hepatic enzyme abnormalities

Skin and subcutaneous tissue disorders

Common	alopecia, acne, rash
Uncommon	hirsutism, urticaria, pruritus, chloasma
Rare	lipodystrophy, dermatitis, ecchymosis, scleroderma, skin striae

Musculoskeletal and connective tissue disorders

Common	Back pain, pain in extremity
Rare	arthralgia, muscle spasms, osteoporosis, osteoporotic fractures

Reproductive system and breast disorders

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

General disorders and administration site conditions

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

Investigations

Very common	weight increased, weight decreased
Rare	decreased bone density, decreased glucose tolerance, abnormal cervical smear

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 [RH084 trade name]

The absorption characteristics of [RH084 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	**Mean value* (±standard deviation)**
	Medroxyprogesterone acetate
Maximum concentration (C_{max}) pg/mL	2299 ± 1051
Area under the curve ($AUC_{0-\infty}$), a measure of the extent of absorption ng.h/mL	3275 ± 774
Time to attain maximum concentration (T_{max}) hour	234 ± 545

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)	20 ± 3 L
Plasma proteinbinding *in vitro*	90-95 %
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 6 weeks (following intramuscular injection)
Mean systemic clearance (Cl/F)	1600-4000 L/day
% 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

Polyethylene glycol 3350

Polysorbate 80 (Tween 80)

Sodium chloride

Methyl paraben

Propyl paraben
Sodium hydroxide (for adjustment of pH)
Hydrochloric acid (for adjustment of pH)
Water for injections

This medicine is essentially 'sodium-free'. It contains less than 1 mmol sodium (23 mg) per vial.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30ºC. Do not freeze.

Store vials in the cartons to protect from light.

6.5 Nature and contents of container

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 sterile suspension. Available in packs of 1's and 20's.

6.6 Special precautions for disposal and other handling

Shake the vial well just before use in order to obtain a homogeneous suspension.

Discard any unused contents in accordance with local requirement.

7. SUPPLIER

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8. WHO REFERENCE NUMBER (WHO Prequalification Programme)

RH084

9. DATE OF PREQUALIFICATION

05 February 2020

10. DATE OF REVISION OF THE TEXT

June 2025

References

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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