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

[RH065 trade name]†

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1.5mg levonorgestrel.

Excipients with potential clinical effect:

Each tablet also contains about 137 mg of lactose monohydrate.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

Off-white, round, uncoated tablets. They are flat on the top and bottom with bevelled edges. The tablets have 'UP' debossed (stamped into) on one side and are plain on the other side. The tablets are about 8 mm in diameter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

[RH065 trade name] is indicated for emergency contraceptive to prevent pregnancy following unprotected intercourse or a known or suspected contraceptive failure.

4.2 Posology and method of administration

[RH065 trade name] should be taken as soon as possible after unprotected intercourse, at most within 5 days but preferably within 3 days.

The dose of [RH065 trade name] is 1 tablet as soon as possible after unprotected intercourse.

Women who have used enzyme-inducing drugs during the last 4 weeks are recommended to take a double dose of levonorgestrel (i.e. 2 tablets taken together).

If vomiting occurs within 3 hours of taking [RH065 trade name], the woman should take another dose immediately. If vomiting continues, an alternative method of emergency contraception should be used, including use of the intravaginal route.

After using emergency contraception, a local barrier method (condom, diaphragm, spermicide, cervical cap) is recommended until the next menstrual period starts. The use of [RH065 trade name] does not contraindicate the continuation of regular hormonal contraception.

Method of administration

For oral administration. The tablet can be taken at any time.

4.3 Contraindications

Hypersensitivity to levonorgestrel or to any of the excipients listed in section 6.1.

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

4.4 Special warnings and precautions for use

Emergency contraception cannot interrupt an established pregnancy. When advising the woman on the use of this medicine, it is important to ask for signs and symptoms of early pregnancy. If any of these apply, pregnancy should be excluded.

Use of emergency contraception does not protect against sexually transmitted diseases.

Severe malabsorption syndromes, such as Crohn's disease, might impair the efficacy of [RH065 trade name].

Limited and inconclusive data suggest that the efficacy of emergency contraception using levonorgestrel may be reduced with increasing body weight or body mass index (BMI). All women should use emergency contraception as soon as possible after unprotected intercourse, regardless of weight or BMI.

If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse more than 5 days earlier in the same menstrual cycle, conception may have occurred. In such a case [RH065 trade name] may be ineffective in preventing pregnancy.

After taking [RH065 trade name], menstrual periods are usually normal but can sometimes occur earlier or later than expected by a few days. Repeated administration within a menstrual cycle may disturb the cycle.

However, if the woman's menstrual period is delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual periods or if pregnancy is suspected for any reason, the woman should have a pregnancy test.

Any regular contraceptive method can be started immediately after the use of [RH065 trade name].

Excipients

The tablet contains lactose monohydrate. Patients with congenital lactase deficiency, galactosaemia or glucose-galactose intolerance must not be given this medicine unless strictly necessary.

The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance 'in other patients'.

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 metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers, mainly CYP3A4 enzyme inducers.

Drugs suspected of having the capacity to reduce the efficacy of levonorgestrel include barbiturates (including primidone), bosentan, carbamazepine, efavirenz, felbamate, griseofulvin, lumacaftor, oxcarbazepine, phenytoin, rifabutin, rifampicin, ritonavir, St John's wort (*Hypericum perforatum*), and topiramate.

For women who have used enzyme-inducing drugs in the past 4 weeks and need emergency contraception, a double-dose of levonorgestrel should be taken (see section 4.2).

Medicines containing levonorgestrel may increase the risk of ciclosporin toxicity due to possible inhibition of ciclosporin metabolism.

4.6 Fertility, pregnancy and breastfeeding

Pregnancy

[RH065 trade name] should not be used during pregnancy. It will not interrupt the pregnancy. In case of failure of this emergency contraception and developing pregnancy, epidemiological studies indicate no adverse effects on the fetus.

Breast-feeding

Levonorgestrel passes into breast milk. However, breast-feeding is not considered a restriction to the use of [RH065 trade name].

Fertility

Levonorgestrel use may sometimes lead to earlier or later ovulation date. These changes can result in modified fertility date. Although there are no fertility data in the long term, rapid return to fertility is expected after use of [RH065 trade name].

4.7 Effects on ability to drive and use machines

[RH065 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

Because clinical trials were conducted under widely varying conditions, adverse reaction rates cannot be directly compared between drugs and they may not reflect the rates encountered in clinical practice.

The most commonly reported undesirable effect was nausea.

The undesirable effects of levonorgestrel are listed below by body system or organ. Frequencies are defined as 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).

Nervous system disorders	
Very common	headache
Common	dizziness
Gastrointestinal disorders	
Very common	nausea, lower abdominal pain
Common	diarrhoea, vomiting
Very rare	abdominal pain
Skin and subcutaneous tissue disorders	
Very rare	rash, urticaria, pruritus
Reproductive system and breast disorders	
Very common	bleeding not related to menses (bleeding patterns temporarily disturbed but usually the next menstrual period occurs within 5–7 days of the expected time)
Common	menses delayed more than 7 days (pregnancy should be ruled out if delayed by more than 5 days), irregular menstruation, breast tenderness
Very rare	pelvic pain, dysmenorrhoea
General disorders and administration site conditions	
Very common	fatigue
Very rare	face oedema

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

There have been no reports of any serious damage to health caused by an overdose.

Symptoms that may occur in overdose include: nausea, vomiting and mild vaginal bleeding. There is no specific antidote; treatment should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sex hormones and modulators of the genital system, emergency contraceptives, ATC code: G03AD01

Mechanism of action

With the recommended regimen, levonorgestrel is thought to work mainly by preventing ovulation and fertilisation if intercourse has taken place in the pre-ovulatory phase, when the likelihood of fertilisation is the highest. It is not effective once implantation has begun.

Clinical efficacy and safety

Efficacy

Randomised, double-blind clinical studies found that a 1.5-mg single dose of levonorgestrel (taken within 72 hours of unprotected sex) prevented over 84% of expected pregnancies (compared with 79% when two 750-microgram tablets were taken 12 hours apart).

A prospective observational study involving 305 women found an overall failure rate of 2.3% with levonorgestrel emergency contraceptive tablets. The failure rate in women under 18 years (2.6%) was comparable to the failure rate in women 18 years and over (2.0%).

Data on the effect of high body-weight or high BMI on contraceptive efficacy of levonorgestrel emergency contraception are limited and inconclusive.

Safety

With the recommended regimen as emergency contraceptive, levonorgestrel is not expected to significantly modify blood clotting factors, or lipid and carbohydrate metabolism.

5.2 Pharmacokinetic properties

The absorption characteristics of [RH065 trade name] have been determined after administration of one levonorgestrel 1.5 mg tablets in healthy volunteers in the fasting state as follows:

Pharmacokinetic variable	**Mean value* (± standard deviation)**
Maximum concentration (C_{max})	17.2 (± 5.7) ng/mL
Area under the curve ($AUC_{0-\infty}$), a measure of the extent of absorption	274 (± 98) ng.h/mL
Time to attain maximum concentration (T_{max})	1.91 (±0.90) hours

*arithmetic mean

Pharmacokinetics of levonorgestrel

Absorption	
Oral bioavailability	Rapid and near complete absorption
Food effect	Information not available
Distribution	

Volume of distribution (mean)	106 L
Plasma protein binding in vitro	33.5% bound to serum albumin and 65% bound to sex hormone binding globulin
Tissue distribution	0.1% of dose transferred to breast milk
Metabolism	
	Metabolism follows the known pathways of steroid metabolism. 100% metabolised by liver.
Active metabolite(s)	None known.
Elimination	
Elimination half life	26 hours
Mean systemic clearance (Cl/F)	1.0–1.5 mL/minute/kg
% of dose excreted in urine	Levonorgestrel metabolites are excreted in about equal proportions in urine and faeces.
% of dose excreted in faeces	Levonorgestrel metabolites are excreted in about equal proportions in urine and faeces.

Pharmacokinetics in obese women

A pharmacokinetic study showed that levonorgestrel concentrations are decreased in obese women (BMI ≥ 30 kg/m^2) (about 50% decrease in C_{max} and AUC_{0-24}), compared to women with normal BMI (< 25 kg/m^2) (Praditpan et al, 2017). Another study also reported that levonorgestrel C_{max} was lower by about 50% in obese women compared to those with normal BMI; doubling the dose (3 mg) in obese women appeared to produce plasma concentration levels similar to those in women with normal BMI who received 1.5 mg of levonorgestrel (Edelman et al, 2016). The clinical relevance of these data is unclear.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of chronic toxicity, mutagenicity and carcinogenicity potential.

Animal experiments with levonorgestrel have shown virilisation of female fetuses at high doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

Maize starch

Poloxamer

Povidone

Colloidal silicon dioxide

Magnesium stearate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

60 months

6.4 Special precautions for storage

Do not store above 30°C. Store tablets in the blisters in the provided carton in order to protect from light.

6.5 Nature and contents of container

Clear colourless plastic (PVC/PVDC) on aluminium foil blister cards, each containing one tablet. One blister card is packed in a one carton. 20 such cartons are packed in a one master carton.

Special precautions for disposal and other handling

No special requirements.

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

7. SUPPLIER

HLL Lifecare Limited (A Government of India Enterprise)

Unipill Block,

Kanagala, Belagavi District,

Karnataka-591225

India

Tel: +91-8333-279239/244/289/543

E-mail: unipill@lifecarehll.com

8. WHO REFERENCE NUMBER (WHO Prequalification Programme)

RH065

9. DATE OF PREQUALIFICATION

23 April 2018

10. DATE OF REVISION OF THE TEXT

September 2025

References

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Sections 4.2

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Sections 4.4 and 5.2

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Edelman AB, Cherala G, Blue SW, et al. Impact of obesity on the pharmacokinetics of levonorgestrel-based emergency contraception: single and double dosing. Contraception. 2016;94:52–7. doi:10.1016/j.contraception.2016.03.006.

Section 5.1

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Creinin MD, Schlaff W, Archer DF, et al. Progesterone receptor modulator for emergency contraception: a randomized controlled trial. Obstet Gynecol. 2006;108:1089–1097. doi:10.1097/01.AOG.0000239440.02284.45.

Glasier AF, Cameron ST, Fine PM, et al. Ulipristal acetate versus levonorgestrel for emergency contraception: a randomised non-inferiority trial and meta-analysis. Lancet. 2010; 375:555–62. doi:10.1016/S0140-6736(10)60101-8

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