1. Name of the medicinal product

Levonorgestrel Tablets BP 0.75 mg

2. Qualitative and quantitative composition

SR. NO.	NAME OF THE INGREDIENTS	PHARMACOPEIAL SPECIFICATION	LABLE CLAIM	OVERAGES %	QTY. / TABLET	PURPOSE
ACTIVE INGREDIENTS						
1.	Levonorgestrel*	BP	0.75 mg	5.00 %	0.788 mg	API
INACTIVE INGREDIENTS						
2.	Beta cyclodextrin	USP	-	0.00 %	22.000 mg	Solubility enhancer
3.	Microcrystalline Cellulose	BP	-	0.00 %	104.220mg	Diluent
4.	Sodium lauryl Sulphate	BP	-	0.00 %	5.000 mg	Surfactant
5.	Polyethylene glycol (Macrogol) 6000	BP	-	0.00 %	4.000 mg	Plasticizer
6.	Povidone	BP	-	0.00 %	4.000 mg	Binder
7.	Isopropyl alcohol**	BP	-	0.00 %	0.050 ml	Solvent
8.	Magnesium Stearate	BP	-	0.00 %	2.000 mg	Lubricant
9.	Purified Talc	BP	-	0.00 %	3.000 mg	Glidant
10.	Croscarmellose sodium	BP	-	0.00 %	3.000 mg	Disintegrant
11.	Colloidal silicon dioxide	USP	-	0.00 %	2.000 mg	Glidant
12.	Hydroxypropylmethyl cellulose (E-15)	BP	-	0.00 %	3.430 mg	Polymer
13.	Purified talc	BP	-	0.00 %	0.245 mg	Polisher
14.	Titanium dioxide	BP	-	0.00 %	0.245 mg	Opacifier
15.	Polyethylene glycol (Macrogol) 6000	BP	-	0.00 %	0.980 mg	Plasticizer
16.	Titanium dioxide	BP	-	0.00 %	0.100 mg	Colour
17.	Isopropyl alcohol**	BP	-	0.00 %	0.500 ml	Solvent
18.	Acetone**	BP	-	0.00 %	0.070 ml	Solvent

*5.00 % overages are added on label claim.

**Evaporates during manufacturing & does not remain in final product.

3. Pharmaceutical form

Oral Tablet

4. Clinical particulars

4.1 Therapeutic indications

Levonorgestrel is used by women to prevent pregnancy after birth control failure (such as a broken condom) or unprotected sex. This medication is an emergency contraceptive and should not be used as a regular form of birth control. It is a progestin hormone that works mainly by preventing the release of an egg (ovulation) during your menstrual cycle. It also makes vaginal fluid thicker to help prevent sperm from reaching an egg (fertilization) and changes the lining of the uterus (womb) to prevent attachment of a fertilized egg.

4.2 Posology and method of administration

For oral administration: One tablet should be taken as soon as possible, preferably within 12 hours and no later than 72 hours after unprotected intercourse.
If vomiting occurs within three hours of taking the tablet another tablet should be taken immediately. The patient should contact her doctor, family planning clinic or pharmacist for advice and another tablet.
Levonorgestrel Tablet can be used at any time during the menstrual cycle unless menstrual bleeding is overdue.
After using emergency contraception it is recommended to use a barrier method (e.g. condom, diaphragm or cap) until the next menstrual period starts. The use of Levonorgestrel Tablet does not contraindicate the continuation of regular hormonal contraception. Children: Levonorgestrel Tablet is not recommended for use by young women under 16 years of age without medical supervision.

4.3 Contraindications

Hypersensitivity to the active substance levonorgestrel or any of the excipients.

4.4 Special warnings and precautions for use

Ectopic Pregnancy: Women who become pregnant or complain of lower abdominal pain after taking levonorgestrel tablets, 0.75 mg should be evaluated for ectopic pregnancy. Levonorgestrel tablets, 0.75 mg are not effective in terminating an existing pregnancy. Effect on menses: Levonorgestrel tablets, 0.75 mg may alter the next expected menses. If menses is delayed beyond 1 week, pregnancy should be considered. STI/HIV: Levonorgestrel tablets, 0.75 mg does not protect against STI/HIV.

4.5 Interaction with other medicinal products and other forms of interaction

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some drugs may cause emergency birth control to work less well by decreasing the amount of birth control hormones in your body. This effect can result in pregnancy. Examples include griseofulvin, modafinil, rifamycins (such as rifampin, rifabutin), St. John's wort, drugs used to treat seizures (such as barbiturates, carbamazepine, felbamate, phenytoin, primidone, topiramate), HIV drugs (such as nelfinavir, nevirapine), among others. Talk to your doctor or pharmacist for more details.

4.6 Pregnancy and lactation

Pregnancy: Levonorgestrel Tablet should not be given to pregnant women. It will not interrupt a pregnancy. In the case of continued pregnancy, limited epidemiological data indicate no adverse effects on the foetus but there are no clinical data on the potential consequences if doses greater than 1.5 mg of levonorgestrel are taken.
Lactation: Levonorgestrel is secreted into breast milk. Potential exposure of an infant to levonorgestrel can be reduced if the breast-feeding woman takes the tablet immediately after feeding and avoids nursing following Levonorgestrel Tablet administration.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

The most common adverse reactions (≥10%) in the clinical trial included menstrual changes (26%), nausea (23%), abdominal pain (18%), fatigue (17%), headache (17%) and dizziness (11%), and breast tenderness (11%).

4.9 Overdose

Serious undesirable effects have not been reported following acute ingestion of large doses of oral contraceptives. Overdose may cause nausea, and withdrawal bleeding may occur. There are no specific antidotes and treatment should be symptomatic.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Emergency contraceptives **ATC code:** G03AD01
Levonorgestrel is a progestin or a synthetic form of the naturally occurring female sex hormone, progesterone. In a woman's normal menstrual cycle, an egg matures and is released from the ovaries (ovulation). The ovary then produces progesterone, preventing the release of further eggs and priming the lining of the womb for a possible pregnancy. If pregnancy occurs, progesterone levels in the body remain high, maintaining the womb lining. If pregnancy does not occur, progesterone levels in the body fall, resulting in a menstrual period. Levonorgestrel tricks the body processes into thinking that ovulation has already occurred, by maintaining high levels of the synthetic progesterone. This prevents the release of eggs from the ovaries.

5.2 Pharmacokinetic properties

Absorption
No specific investigation of the absolute bioavailability of levonorgestrel tablets in humans has been conducted. However, literature indicates that levonorgestrel is rapidly and completely absorbed after oral administration (bioavailability about 100%) and is not subject to first pass metabolism. After a single dose of levonorgestrel tablets (0.75 mg) administered to 16 women under fasting conditions, maximum serum concentrations of levonorgestrel are 14.1 ± 7.7 ng/mL (mean ± SD) at an average of 1.6 ± 0.7 hours. No formal study of the effect of food on the absorption of levonorgestrel has been undertaken.

Distribution
Levonorgestrel in serum is primarily protein bound. Approximately 50% is bound to albumin and 47.5% is bound to sex hormone binding globulin (SHBG).

Metabolism
Following a single oral dosage, levonorgestrel does not appear to be extensively metabolized by the liver. The primary metabolites are 3α,5β- and 3α,5α-tetrahydrolevonorgestrel with 16β-hydroxynorgestrel also identified. Together, these account for less than 10% of parent plasma levels. Urinary metabolites hydroxylated at the 2α and 16β positions have also been identified. Small amounts of the metabolites are present in plasma as sulfate and glucuronide conjugates.

Excretion
The elimination half-life of levonorgestrel following single dose administration as levonorgestrel tablets (0.75 mg) is 24.4 ± 5.3 hours. Excretion following single dose administration as emergency contraception is unknown, but based on chronic, low-dose contraceptive use, levonorgestrel and its metabolites are primarily excreted in the urine, with smaller amounts recovered in the feces.

5.3 Preclinical safety data

Animal experiments with levonorgestrel have shown virilisation of female fetuses at high doses.
Preclinical data from conventional studies on chronic toxicity, mutagenicity and carcinogenicity reveal no special hazard for humans.

6. Pharmaceutical particulars

6.1 List of Excipients

- Beta cyclodextrin
- Croscarmellose Sodium
- Sodium lauryl Sulphate
- Microcrystalline Cellulose
- Isopropyl Alcohol
- Povidone
- Magnesium Stearate
- Purified Talc
- Colloidal Silicon Dioxide
- Acetone
- Hydroxypropylmethyl cellulose (E-15)

- Titanium dioxide
- Polyethylene glycol (Macrogol) 6000

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store in a dry place at a temperature below 30°C.

6.5 Nature and contents of container

2 Tablets Alu-PVC Blister Pack, packed in printed and laminated carton.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Marketing authorisation holder

West Coast Pharmaceutical Works Ltd, Ahmedabad

8. Marketing authorisation number(s)

Not applicable.

9. Date of first authorisation/renewal of the authorisation

Not applicable.

10. Date of revision of the text

August, 2018