1.3.1 Package Insert / Summary of Product Characteristics (SmPC)

Please refer to the Pronta 1 Package Insert overleaf on pages 2 – 11. A copy of the proposed PI artwork is included on pages 12 – 13.

Please note:

The Pronta 1 Package Insert is based on the current SmPC (please refer to Module 1.10.4 for a copy of the current SmPC) and has been wholly aligned to the SmPC. Whilst Pronta 1 is a WHO prequalified product, the Applicant is seeking registration in the ZaZiBoNa countries (though not via the ZaZiBoNa process) and as such, a single Package Insert has been created to satisfy the requirements of the ZaZiBoNa Regulatory Agencies.

PROPOSED PACKAGE INSERT

SCHEDULING STATUS / CATEGORY OF MEDICINE

Botswana: S2

Namibia: NS1

Zambia: POM

Zimbabwe: PP

PROPRIETARY NAME AND DOSAGE FORM

PRONTA 1 tablet

COMPOSITION

Active pharmaceutical ingredient: Levonorgestrel.

Each tablet contains 1.5 mg Levonorgestrel Ph. Eur.

Contains Lactose.

Inactive ingredients

Colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, polyvinyl pyrrolidone K-25.

PHARMACOLOGICAL CLASSIFICATIONS

Botswana & Zambia: Pharmacotherapeutic group: Emergency Contraceptive - ATC code: G 03 AD 01

Namibia: A18.7 Contraceptive preparations

Zimbabwe: 21.2.2 Progesterone - only oral contraceptives

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

The precise mode of action of PRONTA 1 is not known.

At the recommended regimen, levonorgestrel is thought to work mainly by preventing ovulation and fertilisation if the intercourse has taken place in the preovulatory phase, when the likelihood of

fertilisation is the highest. It may also cause endometrial changes that discourage implantation. It is not effective once implantation has begun.

Efficacy: Results from a randomised, double-blind clinical study conducted in 2001 (Lancet 2002; 360: 1803-1810) showed that a 1.5-mg single dose of levonorgestrel (taken within 72 hours of unprotected sex) prevented 84 % of expected pregnancies (compared with 79 % when two 750-microgram tablets were taken 12 hours apart).

It is therefore, recommended that PRONTA 1 tablet is taken as soon as possible (and no later than 72 hours) after unprotected intercourse.

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

Safety: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a medicine cannot be directly compared to rates in the clinical trials of another medicine and may not reflect the rates observed in clinical practice.

A double-blind, controlled clinical trial in 1,955 evaluable women compared the efficacy and safety of Levonorgestrel (one 0.75 mg tablet of levonorgestrel taken within 72 hours of unprotected intercourse, and one tablet taken 12 hours later) to the Yuzpe regimen (two tablets each containing 250 micrograms levonorgestrel and 50 micrograms ethinylestradiol, taken within 72 hours of intercourse, and two tablets taken 12 hours later).

Pharmacokinetic properties

Pharmacokinetic Parameter	Test formulation (T) arithmetic mean ± SD (*)	Reference (R) arithmetic mean ± SD (*)	log-transformed parameters	
			Ratio T/R (%)	Conventional 90 % CI (ANOVAlog)
t_{max} (hour)	2.13 (1 - 4)	2.13 (1 - 4)	-	-
C_{max} (ng/ml)	20.1 ± 6.6	17.5 ± 7.1	118.0	111.6 – 124.9

	(19.3)	(16.3)		
AUC_{0-72}	318 ± 138	312 ± 153	105.2	98.5 – 112.3
(ng·hour/ml)	(289)	(275)		

* geometric mean

Levonorgestrel is not excreted as metabolites. Levonorgestrel metabolites are excreted in about equal proportions in urine and faeces. The biotransformation follows the known pathways of steroid metabolism, the levonorgestrel is hydroxylated in the liver and the metabolites are excreted as glucuronide conjugates.

No pharmacologically active metabolites are known.

Levonorgestrel is bound to serum albumin and sex hormone binding globulin (SHBG). Only about 1.5 % of the total serum levels are present as free steroid, but 65 % are specifically bound to SHBG. The absolute bioavailability of levonorgestrel was determined to be almost 100 % of the dose administered.

About 0.1 % of the maternal dose can be transferred via milk to the nursed infant.

Preclinical safety data

Non-clinical data reveal no special hazard for humans, beyond the information included in this leaflet. Animal experiments with levonorgestrel have shown virilisation of female foetuses at high doses

INDICATIONS

Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.

CONTRAINDICATIONS

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

WARNINGS AND SPECIAL PRECAUTIONS:

Emergency contraception is not effective in terminating an existing pregnancy.

Emergency contraception is an occasional method. It should **not** replace a regular contraceptive method.

Emergency contraception does not prevent a pregnancy in every instance.

Efficacy appears to decline with time (see “PHARMACOLOGICAL PROPERTIES, Pharmacodynamic Properties”).

If there is uncertainty about the timing of the unprotected intercourse or if the woman has had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with PRONTA 1 following the second act of intercourse may therefore be ineffective in preventing pregnancy. If menstrual periods are delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason, pregnancy should be ruled out.

If pregnancy occurs after treatment with PRONTA 1, the possibility of an ectopic pregnancy should be considered, especially in women in whom severe abdominal pain or fainting occurs, or if there is a history of ectopic pregnancy, Fallopian tube surgery or pelvic inflammatory disease. The absolute risk of ectopic pregnancy is likely to be low, as levonorgestrel prevents ovulation and fertilisation. Ectopic pregnancy may continue despite uterine bleeding. Therefore, PRONTA 1 is not recommended for women at risk of ectopic pregnancy (history of salpingitis or of ectopic pregnancy).

PRONTA 1 is not recommended in patients with severe hepatic dysfunction.

Severe malabsorption syndromes, such as Crohn’s disease, might impair the efficacy of PRONTA 1.

The tablet contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

After taking PRONTA 1, menstrual periods are usually normal and occur at the expected date. They can sometimes occur earlier or later than expected by a few days. Women should be advised to see a health care provider to initiate or adopt a method of regular contraception. If no withdrawal bleed occurs in the next pill-free period following the use of PRONTA 1 after regular hormonal contraception, pregnancy should be ruled out.

Repeated administration within a menstrual cycle is not advisable because of the possibility of disturbing the cycle.

Any regular contraceptive method can be started immediately after the use of PRONTA 1 emergency contraceptive pills. If the woman starts a hormonal contraceptive:

- she needs to abstain from sexual intercourse or use barrier contraception for 7 days;
- she should be advised to have a pregnancy test if she does not have a withdrawal bleed within 3 weeks.

PRONTA 1 is not as effective as a conventional regular method of contraception and is suitable only as an emergency measure. Women who present for repeated courses of emergency contraception should be advised to consider long-term methods of contraception.

Use of emergency contraception does not replace the necessary precautions against sexually transmitted diseases.

Effects on ability to drive and use machines

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

INTERACTIONS

The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers.

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

Significant changes (increase or decrease) in the plasma levels of the progestogen have been noted in some cases of co-administration with HIV protease inhibitors or with non-nucleoside reverse transcriptase inhibitors. The potential interaction may require close monitoring, alteration of medicine dosage or timing of administration.

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

PREGNANCY AND LACTATION

Pregnancy

PRONTA 1 should not be given to pregnant women. It will not interrupt the pregnancy.
In case of failure of this emergency contraception and developing pregnancy, epidemiological studies indicate no adverse effects of progestogens on the foetus. There are no clinical data on the potential consequences if doses greater than 1.5 mg levonorgestrel are taken (see "PHARMACOLOGICAL PROPERTIES, Preclinical safety data").

Lactation

Levonorgestrel is secreted into breast milk. Potential exposure of an infant to levonorgestrel can be reduced if the breast-feeding woman takes the tablets immediately after feeding and avoids nursing following each PRONTA 1 administration.

Fertility

Clinical experience reveal no effect on fertility after use of levonorgestrel. Non-clinical studies show no evidence of adverse effects in animals (see “PHARMACOLOGICAL PROPERTIES, Preclinical safety data”).

DOSAGE AND DIRECTIONS FOR USE

For oral administration, the treatment course comprises a single tablet.

The highest efficacy is achieved if the tablet is taken as soon as possible (and no later than 72 hours) after unprotected intercourse.

If vomiting occurs within two hours of taking the tablet, another tablet should be taken immediately. If repeated vomiting occurs, the tablet may be administered vaginally.

PRONTA 1 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 local barrier method (condom, cervical cap) until the next menstrual period starts. The use of PRONTA 1 does not contraindicate the continuation of regular hormonal contraception.

PRONTA 1 is not recommended for use by young women aged under 16 years without medical supervision.

SIDE EFFECTS

The most common adverse events (>10 %) in the clinical trial for women receiving levonorgestrel 0.75 mg included nausea (23 %), abdominal pain (18 %), fatigue (17 %), headache (17 %), dizziness (11 %), breast tenderness (11 %) and menstrual changes (26 %).
The table below shows those adverse events that occurred in ≥ 5 % of levonorgestrel 0.75 mg users.

Adverse events in ≥ 5 % of women, by frequency	
Adverse events	**Levonorgestrel 0.75 mg (n = 977)**

Nausea	23.1 %
Abdominal pain	17.6 %
Fatigue	16.9 %
Headache	16.8 %
Heavier menstrual bleeding	13.8 %
Lighter menstrual bleeding	12.5 %
Dizziness	11.2 %
Breast tenderness	10.7 %
Vomiting	5.6 %
Diarrhoea	5.0 %

Bleeding patterns may be temporarily disturbed, but most women will have their next menstrual period within 7 days of the expected time.

If the next menstrual period is more than 5 days overdue pregnancy should be ruled out.

The following very rare (less than 1 in 10 000) additional side effects have been reported in post-marketing surveillance:

Gastrointestinal disorders	abdominal pain
Skin and subcutaneous tissue disorders	rash, urticarial, pruritus
Reproductive system and breast disorders	pelvic pain, dysmenorrhea
General disorders and administration-site conditions	face oedema

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

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

IDENTIFICATION

Round, white to off white, uncoated flat tablets debossed with “145” on one side and other side plain.

PRESENTATION

PVC/PVdC-Aluminium blister, containing 1 tablet per blister card. One blister card per carton.

STORAGE INSTRUCTIONS

Do not store above 30°C.

Protect from light.

Store the tablet in the blister in provided carton.

Store all medicines out of sight and reach of children.

SHELF-LIFE

3 years

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

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

REGISTRATION NUMBERS

Botswana: To be allocated

Namibia: 18/21.8.2/0114 (Act No.13 of 2003)

Zambia: 428/001

Zimbabwe: 2018/21.2.2/5594

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Population Services International, South Africa

Block L, 63 Regency Drive, Route 21 Corporate Park

Irene, 0152

South Africa

Tel. +27 87 809 0087

NAME AND ADDRESS OF THE MANUFACTURER

Mylan Laboratories Ltd.

Plot No. 20 & 21, Pharmez, Sarkhej-Bavla, National Highway No. 08A

Near Village Matoda, Taluka Sanand, District Ahmedabad, 382213, Gujarat State

India

DATE OF PUBLICATION OF THE PACKAGE INSERT

Botswana: To be allocated

Namibia: 22 November 2018

Zambia: 30 May 2018

Zimbabwe: 11 October 2018

pronta[1]
Levonorgestrel Tablet
1.5 mg

SCHEDULING STATUS / CATEGORY OF MEDICINE

Botswana:	**S2**
Namibia:	**NS1**
Zambia:	**POM**
Zimbabwe:	**PP**

PROPRIETARY NAME AND DOSAGE FORM

PRONTA 1 tablet

COMPOSITION

Active pharmaceutical ingredient: Levonorgestrel.
Each tablet contains 1.5 mg Levonorgestrel Ph. Eur.
Contains Lactose.

Inactive ingredients

Colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, polyvinyl pyrrolidone K-25.

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Zimbabwe: 21.2.2 Progesterone – only oral contraceptives

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

The precise mode of action of **PRONTA 1** is not known.

At the recommended regimen, levonorgestrel is thought to work mainly by preventing ovulation and fertilisation if the intercourse has taken place in the preovulatory phase, when the likelihood of fertilisation is the highest. It may also cause endometrial changes that discourage implantation. It is not effective once implantation has begun.

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It is therefore, recommended that **PRONTA 1** tablet is taken as soon as possible (and no later than 72 hours) after unprotected intercourse.

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

Safety: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a medicine cannot be directly compared to rates in the clinical trials of another medicine and may not reflect the rates observed in clinical practice.

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Repeated administration within a menstrual cycle is not advisable because of the possibility of disturbing the cycle.

Any regular contraceptive method can be started immediately after the use of **PRONTA 1** emergency contraceptive pills. If the woman starts a hormonal contraceptive:

- she needs to abstain from sexual intercourse or use barrier contraception for 7 days;
- she should be advised to have a pregnancy test if she does not have a withdrawal bleed within 3 weeks.

PRONTA 1 is not as effective as a conventional regular method of contraception

and is suitable only as an emergency measure. Women who present for repeated courses of emergency contraception should be advised to consider long-term methods of contraception.

Use of emergency contraception does not replace the necessary precautions against sexually transmitted diseases.

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

INTERACTIONS
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PREGNANCY AND LACTATION
Pregnancy

PRONTA 1 should not be given to pregnant women. It will not interrupt the pregnancy.

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Levonorgestrel is secreted into breast milk. Potential exposure of an infant to levonorgestrel can be reduced if the breast-feeding woman takes the tablets immediately after feeding and avoids nursing following each **PRONTA 1** administration.

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DOSAGE AND DIRECTIONS FOR USE
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If vomiting occurs within two hours of taking the tablet, another tablet should be taken immediately. If repeated vomiting occurs, the tablet may be administered vaginally.

PRONTA 1 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 local barrier method (condom, cervical cap) until the next menstrual period starts. The use of **PRONTA 1** does not contraindicate the continuation of regular hormonal contraception.

PRONTA 1 is not recommended for use by young women aged under 16 years without medical supervision.

SIDE EFFECTS
The most common adverse events (>10 %) in the clinical trial for women receiving levonorgestrel 0.75 mg included nausea (23 %), abdominal pain (18 %), fatigue (17 %), headache (17 %), dizziness (11 %), breast tenderness (11 %) and menstrual changes (26 %).

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Diarrhoea	5.0 %

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If the next menstrual period is more than 5 days overdue pregnancy should be ruled out.

The following very rare (less than 1 in 10 000) additional side effects have been reported in post-marketing surveillance:

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Skin and subcutaneous tissue disorders	rash, urticarial, pruritus
Reproductive system and breast disorders	pelvic pain, dysmenorrhea
General disorders and administration-site conditions	face oedema

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Serious undesirable effects have not been reported following acute ingestion of large doses of oral contraceptives. Overdose may cause nausea and vomiting; withdrawal bleeding may occur. There are no specific antidotes and treatment should be symptomatic.

IDENTIFICATION
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PRESENTATION
PVC/PVdC-Aluminium blister, containing 1 tablet per blister card. One blister card per carton.

STORAGE INSTRUCTIONS
Do not store above 30°C.
Protect from light.
Store the tablet in the blister in provided carton.
Store all medicines out of sight and reach of children.

SHELF-LIFE
3 years

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING
Any unused product or waste material should be disposed of in accordance with local requirements.

REGISTRATION NUMBERS

Botswana:	To be allocated	S2
Namibia:	18/21.8.2/0114 (Act No. 13 of 2003)	NS1
Zambia:	428/001	POM
Zimbabwe:	2018/21.2.2/5594	PP

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Population Services International, South Africa
Block L, 63 Regency Drive, Route 21 Corporate Park, Irene, 0152
South Africa
Tel. +27 87 809 0087

NAME AND ADDRESS OF THE MANUFACTURER
Mylan Laboratories Ltd.
Plot No.20 & 21, Pharmez, Sarkhej - Bavla, National Highway No.08A, Near Village Matoda, Taluka Sanand, District Ahmedabad, 382213, Gujarat State, India.

DATE OF PUBLICATION OF THE PACKAGE INSERT
Botswana: To be allocated
Namibia: 22 November 2018
Zambia: 30 May 2018
Zimbabwe: 11 October 2018

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