1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

(a) Product Name: Progest Tablet

(b) Strength: Dydrogesterone 10 mg per tablet

(c) Pharmaceutical Dosage Form: Oral Tablet

2. Qualitative and Quantitative Composition

- Dydrogesterone USP

Each tablet contains Dydrogesterone USP

3. Pharmaceutical Form

White to off-white, round shaped, standard bi-convex film coated tablet with both side plain surface.

4. Clinical Particulars

4.1 Therapeutic Indications

- Treatment of dysmenorrhea
- Treatment of endometriosis
- Treatment of secondary amenorrhoea
- Treatment of irregular cycles
- Treatment of dysfunctional uterine bleeding
- Treatment of pre-menstrual syndrome
- Treatment of threatened and habitual abortion, associated with proven progesterone deficiency
- Treatment of infertility due to luteal insufficiency

4.2 Posology and method of administration

For initiation and continuation of treatment of postmenopausal symptoms, the lowest effective dose for the shortest duration should be used.

In general, treatment should start with Dydrogesterone 10 mg tablet. Depending on the clinical response, the dosage can afterwards be adjusted to individual need. If the complaints linked to oestrogen deficiency are not ameliorated the dosage can be increased by using two Dydrogesterone 10 mg tablets.

Starting Progest

In women who are not taking hormone replacement therapy and who are amenorrhoeic, or women who switch from a continuous combined hormone replacement therapy, treatment may be started on any convenient day. In women transferring from a cyclic or continuous sequential HRT regimen, treatment should begin the day following completion of the prior regimen.

Administration

For the first 14 days during a 28-cycle, one tablet containing oestradiol is taken daily; during the following 14 days one tablet containing oestradiol and dydrogesterone is taken.

After a cycle of 28 days, on the 29th day, a new 28-day cycle begins. This means that the treatment should be taken continuously without a break between packs. Dydrogesterone can be taken with or without food.

The days of the week are printed on the back of the blister strips. Firstly, the tablets from the part marked with arrow 1 should be taken, then all the tablets from the part marked with arrow 2 should be taken.

If a dose has been forgotten, it should be taken as soon as possible. When more than 12 hours have elapsed, it is recommended to continue with the next dose without taking the forgotten tablet. The likelihood of breakthrough bleeding or spotting may be increased.

Paediatric population:

There is no relevant indication for the use of Progest in the paediatric population.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients. Known or suspected progestogen dependent neoplasms. Undiagnosed vaginal bleeding.

4.4 Special warning and precautions for use

For the treatment of postmenopausal symptoms, HRT should only be initiated for symptoms that adversely affect quality of life. In all cases, a careful appraisal of the risks and benefits should be undertaken at least annually and HRT should only be continued as long as the benefit outweighs the risk.

Evidence regarding the risks associated with HRT in the treatment of premature menopause is limited. Due to the low level of absolute risk in younger women, however, the balance of benefits and risks for these women may be more favourable than in older women.

Medical examination/follow up

Before initiating or reinstituting HRT, a complete personal and family medical history should be taken. Physical (including pelvic and breast) examination should be guided by this and by the contraindications and warnings for use. During treatment, periodic check-ups are recommended of a frequency and nature adapted to the individual woman. Women should be advised what changes in their breasts should be reported to their doctor or nurse (see 'Breast cancer' below). Investigations, including appropriate imaging tools, e.g. mammography, should be carried out in accordance with currently accepted screening practices, modified to the clinical needs of the individual.

Conditions which need supervision

If any of the following conditions are present, have occurred previously, and/or have been aggravated during pregnancy or previous hormone treatment, the patient should be closely supervised. It should be taken into account that these conditions may recur or be aggravated during treatment with Progest, in particular:

- Leiomyoma (uterine fibroids) or endometriosis

- Risk factors for thromboembolic disorders (see below)

- Risk factors for oestrogen dependent tumours, e.g. 1st degree heredity for breast cancer

- Hypertension

- Liver disorders (e.g. liver adenoma)

- Diabetes mellitus with or without vascular involvement

- Cholelithiasis

- Migraine or (severe) headache

- Systemic lupus erythematosus

- A history of endometrial hyperplasia (see below)

- Epilepsy

- Asthma

- Otosclerosis

Reasons for immediate withdrawal of therapy:

Therapy should be discontinued in cases where a contra-indication is discovered and in the following situations:

- Jaundice or deterioration in liver function

- Significant increase in blood pressure

- New onset of migraine-type headache

- Pregnancy

Endometrial hyperplasia and carcinoma

In women with an intact uterus the risk of endometrial hyperplasia and carcinoma is increased when oestrogens are administered alone for prolonged periods. The reported increase in endometrial cancer risk among oestrogen-only users varies from 2- to 12-fold greater compared with non-users, depending on the duration of treatment and oestrogen dose (see section 4.8). After stopping treatment risk may remain elevated for at least 10 years.

The addition of a progestogen cyclically for at least 12 days per month/28 day cycle or continuous combined oestrogen-progestogen therapy in non-hysterectomised women prevents the excess risk associated with oestrogen-only HRT.

Break-through bleeding and spotting may occur during the first months of treatment. If break-through bleeding or spotting appears after some time on therapy, or continues after treatment has been discontinued, the reason should be investigated, which may include endometrial biopsy to exclude endometrial malignancy.

Breast cancer

The overall evidence shows an increased risk of breast cancer in women taking combined oestrogen-progestogen or oestrogen-only HRT, that is dependent on the duration of taking HRT.

Combined oestrogen-progestogen therapy

The randomised placebo-controlled trial, the Women's Health Initiative study (WHI) and a meta-analysis of prospective epidemiological studies are consistent in finding an increased risk of breast cancer in women taking combined oestrogen-progestogen for HRT that becomes apparent after about 3 (1-4) years (see Section 4.8).

The excess risk becomes apparent within a few years of use but returns to baseline within a few (at most five) years after stopping treatment.

HRT, especially oestrogen-progestogen combined treatment, increases the density of mammographic images which may adversely affect the radiological detection of breast cancer.

Oestrogen-only therapy

The WHI trial found no increase in the risk of breast cancer in hysterectomised women using oestrogen-only HRT. Observational studies have mostly reported a small increase in risk of having breast cancer diagnosed that is lower than that found in users of oestrogen-progestogen combinations (see section 4.8).

Results from a large meta-analysis showed that after stopping treatment, the excess risk will decrease with time and the time needed to return to baseline depends on the duration of prior HRT use. When HRT was taken for more than 5 years, the risk may persist for 10 years or more.

HRT, especially oestrogen-progestogen combined treatment, increases the density of mammographic images which may adversely affect the radiological detection of breast cancer.

Ovarian cancer

Ovarian cancer is much rarer than breast cancer. Epidemiological evidence from a large meta-analysis suggests a slightly increased risk in women taking oestrogen-only or combined oestrogen-progestogen HRT, which becomes apparent within 5 years of use and diminishes over time after stopping. Some other studies including the WHI trial suggest that use of combined HRTs may be associated with a similar or slightly smaller risk (see Section 4.8).

Venous thromboembolism

- HRT is associated with a 1.3-3 fold risk of developing venous thromboembolism (VTE), i.e. deep vein thrombosis or pulmonary embolism. The occurrence of such an event is more likely in the first year of HRT than later.

- Patients with known thrombophilic states have an increased risk of VTE and HRT may add to this risk. HRT is therefore contraindicated in these patients (see section 4.3)

- Generally, recognised risk factors for VTE include, use of oestrogens, older ages, major surgery, prolonged immobilisation, severe obesity (BMI>30 kg/m2), pregnancy/postpartum period, systemic lupus erythematosus (SLE), and cancer. There is no consensus about the possible role of varicose veins in VTE.

As in all postoperative patients, prophylactic measures need to be considered to prevent VTE following surgery. If prolonged immobilisation is to follow elective surgery temporarily stopping HRT 4 to 6 weeks earlier is recommended. Treatment should not be restarted until the woman is completely mobilised.

- In women with no personal history of VTE but with a first degree relative with a history of thrombosis at young age, screening may be offered after careful counselling regarding its limitations (only a proportion of thrombophilic defects are identified by screening).If a thrombophilic defect is identified which segregates with thrombosis in family members or if the defect is 'severe' (e.g. antithrombin, protein S, or protein C deficiencies or a combination of defects) HRT is contraindicated.

- Women already on chronic anticoagulant treatment require careful consideration of the benefit-risk use of HRT.

- If VTE develops after initiating therapy, the drug should be discontinued. Patients should be told to contact their doctors immediately when they are aware of a potential thromboembolic symptom (e.g. painful swelling of a leg, sudden pain in the chest, dyspnoea).

Coronary artery disease (CAD)

There is no evidence from randomised controlled trials of protection against myocardial infarction in women with or without existing CAD who received combined oestrogen-progestogen or oestrogen-only HRT.

Ischaemic stroke

Combined oestrogen-progestogen and oestrogen-only therapy are associated with an up to 1.5-fold increase in risk of ischaemic stroke. The relative risk does not change with age or time since menopause. However, as the baseline risk of stroke is strongly age-dependent, the overall risk of stroke in women who use HRT will increase with age (see section 4.8).

Other conditions

• HRT use does not improve cognitive function. There is some evidence of increased risk of possible dementia in women who start using continuous combined or oestrogen-only HRT after the age of 65.

• Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

• Women who may be at risk of pregnancy should be advised to adhere to non-hormonal contraceptive methods.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

The efficacy of progestogens might be impaired:

The metabolism of progestogens may be increased by concomitant use of substances known to induce drug-metabolising enzymes, specifically the P450 enzymes 2B6, 3A4, 3A5, 3A7, such as anticonvulsants (e.g. phenobarbital, phenytoin, carbamezapin) and anti-infectives (e.g. rifampicin, rifabutin, nevirapine, efavirenz).

Ritonavir and nelfinavir, although known as strong inhibitors of CYP450 3A4, A5, A7, by contrast exhibit inducing properties when used concomitantly with steroid hormones.

Herbal preparations containing St John's Wort (Hypericum perforatum) may induce the metabolism of oestrogens and progestogens via the CYP450 3A4 pathway.

Clinically an increased metabolism of oestrogens and progestogens may lead to decreased effect and changes in the uterine bleeding profile.

4.6 Fertility, Pregnancy and lactation

From spontaneous surveillance systems to date, there is no evidence that dydrogesterone can not be used during pregnancy.
Dydrogesterone is excreted in the milk of nursing mothers. A risk to the suckling child cannot be excluded. Dydrogesterone should not be used during breast-feeding.

There is no evidence that Dydrogesterone decreases fertility at therapeutic dose.

4.7 Effects on ability to drive and use machine

Progest does not affect the ability to drive and use machines.

4.8 Undesirable effects

The most commonly reported adverse drug reactions of patients treated with dydrogesterone in clinical trials are headache, abdominal pain, breast pain/tenderness and back pain.

The following undesirable effects have been observed with the frequencies indicated below during clinical trials (n=4929):

MedDRA system organ class	Very common ≥1/10	Common ≥1/100, <1/10	Uncommon ≥1/1,000, <1/100	Rare ≥1/10,000, <1/1,000
Infections and infestations		Vaginal candidiasis	Cystitis-like syndrome	
Neoplasms benign, malignant and unspecified			Increase in size of leiomyoma	
Immune system disorders			Hypersensitivity	
Psychiatric disorders		Depression, Nervousness	Influence on libido	
Nervous system disorders	Headache	Migraine, Dizziness		
Cardiac disorders				Myocardial infarction
Vascular disorders			Hypertension, Peripheral vascular disease, Varicose	

			vein, Venous thromboembolism	
Gastrointestinal disorders	Abdominal pain	Nausea, Vomiting, Flatulence	Dyspepsia	
Hepatobiliary disorders			Abnormal hepatic function, occasionally with jaundice asthenia or malaise, and abdominal pain, Gall bladder disorder	
Skin and subcutaneous tissue disorders		Allergic skin reactions (e.g. rash, urticaria, pruritus)		Angioedema, Vascular purpura
Musculoskeletal and connective tissue disorders	Back pain			
Reproductive system and breast disorders	Breast pain/ tenderness	Menstrual disorders (including postmenopausal spotting, metrorrhagia, menorrhagia, oligo-/amenorrhoea, irregular menstruation, dysmenorrhoea), Pelvic pain, Cervical discharge	Breast enlargement, Premenstrual syndrome	
General disorders and administration site reactions		Asthenic conditions (asthenia, fatigue, malaise), Peripheral oedema		
Investigations		Increased weight	Decreased weight	

Breast Cancer risk

• An up to 2-fold increased risk of having breast cancer diagnosed is reported in women taking combined oestrogen-progestogen therapy for more than 5 years.

• The increased risk in users of oestrogen-only therapy is lower than that seen in users of oestrogen-progestogen combinations.

• The level of risk is dependent on the duration of use.

• Absolute risk estimations based on results of the largest randomised placebo-controlled trial (WHI-study) and the largest meta-analysis of prospective epidemiological studies are presented.

Endometrial cancer

Postmenopausal women with a uterus

The endometrial cancer risk is about 5 in every 1000 women with a uterus not using HRT.

In women with a uterus, use of oestrogen-only HRT is not recommended because it increases the risk of endometrial cancer (see section 4.4). Depending on the duration of oestrogen-only use and oestrogen dose, the increase in risk of endometrial cancer in epidemiology studies varied from between 5 and 55 extra cases diagnosed in every 1000 between the ages of 50 and 65.

Adding a progestogen to oestrogen-only therapy for at least 12 days per cycle can prevent this increased risk. In the Million Women Study the use of five years of combined (sequential or continuous) HRT did not increase risk of endometrial cancer (R.R of 1 .0 (0.8-1.2)).

Ovarian cancer

Use of oestrogen-only or combined oestrogen-progestogen HRT has been associated with a slightly increased risk of having ovarian cancer diagnosed (see section 4.4).

A meta-analysis from 52 epidemiological studies reported an increased risk of ovarian cancer in women currently using HRT compared to women who have never used HRT (RR 1.43, 95% CI 1.31-1.56). For women aged 50 to 54 years taking 5 years of HRT, this results in about 1 extra case per 2000 users. In women aged 50 to 54 who are not taking HRT, about 2 women in 2000 will be diagnosed with ovarian cancer over a 5-year period.

Risk of venous thromboembolism

HRT is associated with a 1.3-3-fold increased relative risk of developing venous thromboembolism (VTE), i.e. deep vein thrombosis or pulmonary embolism. The occurrence of such an event is more likely in the first year of using HT. Results of the WHI studies are presented:

Risk of coronary artery disease

• The risk of coronary artery disease is slightly increased in users of combined oestrogen-progestogen HRT over the age of 60.

Risk of ischaemic stroke

• The use of oestrogen-only and oestrogen + progestogen therapy is associated with an up to 1.5-fold increased relative risk of ischaemic stroke. The risk of haemorrhagic stroke is not increased during use of HRT.

• This relative risk is not dependent on age or on duration of use, but as the baseline risk is strongly age-dependent, the overall risk of stroke in women who use HRT will increase with age.

WHI studies combined - Additional risk of ischaemic stroke*[2] over 5 years' use

Age range (years)	Incidence per 1000 women in placebo arm over 5 years	Risk ratio and 95%CI	Additional cases per 1000 HRT users
50-59	8	1.3 (1.1-1.6)	3 (1–5)

No differentiation was made between ischaemic and haemorrhagic stroke

Other adverse reactions have been reported in association with oestrogen/progestogen treatment (including oestradiol/dydrogesterone):

Neoplasms benign, malignant and unspecified:

Oestrogen dependent neoplasms both benign and malignant, e.g. endometrial cancer, ovarian cancer. Increase in size of progestogen dependent neoplasms, e.g. meningioma.

Blood and lymphatic system disorders:

Haemolytic anaemia

Immune system disorders:

Systemic lupus erythematosus

Metabolism and nutrition disorders:

Hypertriglyceridemia

Nervous system disorders:

Probable dementia over the age of 65 (see section 4.4), chorea, exacerbation of epilepsy

Eye disorders:

Steepening of corneal curvature, contact lenses intolerance

Vascular disorders:

Arterial thromboembolism

Gastrointestinal disorders:

Pancreatitis (in women with pre-existing hypertriglyceridemia)

Skin and subcutaneous tissue disorders:

Erythema multiforme, erythema nodosum, chloasma or melasma, which may persist when drug is discontinued.

Musculoskeletal and connective tissue disorders:

Leg cramps

Renal and urinary disorders:

Urinary incontinence

Reproductive system and breast disorders:

Fibrocystic breast disease, uterine cervical erosion

Congenital, familial and genetic disorders:

Aggravated porphyria

Investigations:

Total thyroid hormones increased

4.9 Management of overdose

Limited data are available with regard to overdose in humans. Dydrogesterone was well tolerated after oral dosing (maximum daily dose taken to date in humans 360 mg). No reports of ill-effects from overdose have been recorded. If a large overdose is discovered within two or three hours and treatment seems desirable, gastric lavage is recommended. There are no specific antidotes and treatment should be symptomatic. Aforementioned information is also applicable for overdosing in children.

5. Pharmacological Properties

5.1 Pharmacodynamics Properties

The ATC code is G03DB02.

Dydrogesterone

Dydrogesterone is an orally-active progestogen having an activity comparable to parenterally administered progesterone. As oestrogens promote the growth of the endometrium, unopposed oestrogens increase the risk of endometrial hyperplasia and cancer. The addition of a progestogen greatly reduces the oestrogen-induced risk of endometrial hyperplasia in non-hysterectomised women.

Clinical trial information

Relief of oestrogen-deficiency symptoms and bleeding patterns.

- Relief of menopausal symptoms was achieved during the first few weeks of treatment.

- Regular withdrawal bleeding with Progest occurred in approximately 75-80% of women with a mean duration of 5 days.

Withdrawal bleeding usually started on the day of the last pill of the progestogen phase. Break-through bleeding and/or spotting occurred in approximately 10% of the women; amenorrhoea (no bleeding or spotting) occurred in 21-25% of the women for months 10 to 12 of treatment.

Prevention of osteoporosis

- Evidence from the WHI trial and meta-analysed trials shows that current use of HRT, alone or in combination with a progestogen – given to predominantly healthy women – reduces the risk of hip, vertebral, and other osteoporotic fractures. HRT may also prevent fractures in women with low bone density and/or established osteoporosis, but the evidence for that is limited.

- After two years of treatment with Progest, the increase in lumbar spine bone mineral density (BMD) was 6.7% ± 3.9% (mean ± SD). The percentage of women who maintained or gained BMD in lumbar zone during treatment was 94.5%. For Progest the increase in lumbar spine BMD was 5.2% ± 3.8% (mean ± SD), and the percentage of women with no change or an increase in lumbar spine BMD was 93%.

- Progest also had an effect on hip BMD. The increase after two years of treatment with 1mg oestradiol was 2.7% ± 4.2% (mean ± SD) at femoral neck, 3.5% ± 5.0% (mean ± SD) at trochanter and 2.7%± 6.7% (mean ± SD) at Wards triangle. After two years of treatment with 2mg oestradiol these figures were respectively, 2.6% ± 5.0%; 4.6% ± 5.0% and 4.1% ± 7.4%. The percentage of women who maintained or gained BMD in the 3 hip areas after treatment with 1mg oestradiol was 67-78% and 71-88% after treatment with 2mg oestradiol.

5.2 Pharmacokinetic Properties

Dydrogesterone

• Absorption

Following oral administration, dydrogesterone is rapidly absorbed with a T_{max} between 0.5 and 2.5 hours. The absolute bioavailability of dydrogesterone (oral 20mg dose versus 7.8mg intravenous infusion) is 28%.

The following table provide the mean steady state pharmacokinetic parameters of dydrogesterone (D) and dihydrodydrogesterone (DHD). Data is presented as mean (SD).

Dydrogesterone 10mg		
Parameters	D	DHD
C_{max} (ng/mL)	2.54 (1.80)	62.50 (33.10)
C_{min} (ng/mL)	0.13 (0.07)	3.70 (1.67)
C_{av} (ng/mL)	0.42 (0.25)	13.04 (4.77)
AUC_{0-t} (ng.h/mL)	9.14 (6.43)	311.17 (114.35)

• Distribution

After intravenous administration of dydrogesterone the steady-state volume of distribution is approximately 1400 L. Dydrogesterone and DHD are more than 90% bound to plasma proteins.

• Metabolism

Following oral administration, dydrogesterone is rapidly metabolised to DHD. The levels of the main active metabolite 20 α-dihydrodydrogesterone (DHD) peak about 1.5 hours post dose. The plasma levels of DHD are substantially higher as compared to the parent drug. The AUC and C_{max} ratios of DHD to dydrogesterone are in the order of 40 and 25, respectively. Mean terminal half-lives of dydrogesterone and DHD vary between 5 to 7 and 14 to 17 hours, respectively. A common feature of all metabolites characterised is the retention of the 4,6 diene-3-one configuration of the parent compound and the absence of 17α- hydroxylation. This explains the lack of oestrogenic and androgenic effects of dydrogesterone.

• Elimination

After oral administration of labelled dydrogesterone, on average 63% of the dose is excreted into the urine. Total plasma clearance is 6.4 L/min. Within 72 hours excretion is complete. DHD is present in the urine predominantly as the glucuronic acid conjugate.

• Dose and time dependencies

The single and multiple dose pharmacokinetics are linear in the oral dose range 2.5 to 10mg. Comparison of the single and multiple dose kinetics shows that the pharmacokinetics of dydrogesterone and DHD are not changed as a result of repeated dosing. Steady state was reached after 3 days of treatment.

5.3 Preclinical Safety Data

There are no preclinical safety data of relevance to the prescriber in the target population that are additional to those already included in other sections.

6. Pharmaceutical Particulars

6.1 List of excipients

- Lactose Monohydrate (Spray Dried)
- Microcrystalline Cellulose (PH 102)
- Croscarmellose Sodium
- Colloidal Anhydrous Silica (Aerosil 200)
- Magnesium Stearate
- Opadry White OY-C-7000A
- Dichloromethane
- Methanol
- Carnauba Wax (Powdered)
- Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store in a dry place below 30^0 C protected from light. Keep out of reach of children.

6.5 Nature and contents of container

From the results of the stability study, it is confirmed that Dydrogesterone 10 mg Tablet is stable for 2 years and packed in Alu-PVC/PVDC Blister pack. This Alu-PVC/PVDC Blister packs are further packed in secondary packs (Inner Carton) & finally in paperboard Master carton for providing extra protection.

6.6 Special precautions for disposal and other handling

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

7. Marketing Authorization Holder

Name: Popular Pharmaceuticals Ltd.

Factory Address: 164, Tongi Industrial Area, Tongi, Gazipur-1711, Bangladesh.

1.3.2 Labelling (outer & inner labels)

A-Labeling parameters required for unit carton

1-Product Name: Progest Tablet

2-Dosage Form: Tablet

3-Name of the Active Ingredient(s): Dydrogesterone USP

4-Strength of Active Ingredient(s): Each tablet contains Dydrogesterone USP 10 mg.

5-Batch Number:

6-Manufacturing Date:

7-Expiration Date:

8-Route of Administration: Oral

9-Storage Condition: Store in a dry place below 30°C & protect from light. Keep out of the reach of children.

10-Country's Registration Number if Any: 336-352-056

11-Name and Address of marketing Authorization Holder/ or Name and Address of manufacturer.

POPULAR PHARMACEUTICALS LTD.

Plant address:

164, Tongi Industrial Area, Tongi.

Gazipur-1711, Bangladesh.

12-Special Labeling (if applicable) eg. Sterile, External use, Cytotoxic, Alcohol content, Animal Origin

13-Recommended daily allowance if any (=can or cannot provide):

14-Warning (if applicable): Monitor closely for loss of vision, proptosis, diplopia, migraine, signs and symptoms of embolic disorders. CVD or renal impairment, epilepsy, asthma, other conditions which may be aggravated by fluid retention. Lactation.

15-Pack size (Unit/Volume): Each box contains 2 x 15 Tablets in blister pack.

16-Name/strength of preservative: NA

B-Labeling Parameters Required for INNER LABEL:

Not applicable

C-Labeling Parameters required for Blister/ Strips:

1-Product Name: Progest Tablet

2-Dosage Form: Tablet

3-Name of the Active Ingredient(s): Dydrogesterone USP

4-Batch Number:

5-Manufacturing Date:

6-Expiration Date:

7-Route of Administration: Oral

8-Country's Registration Number if Any: 336-352-056

9-Name and Address of marketing Authorization Holder/ or Name and Address of manufacturer.

POPULAR PHARMACEUTICALS LTD.

Plant address:

164, Tongi Industrial Area, Tongi.

Gazipur-1711, Bangladesh.