SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Trust Daisy 1 EC Tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1.5 mg levonorgestrel

Excipients: For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

White, round flat bevel edge tablet, one side having logo “E 1.5” and another side is plain.

4. CLINICAL PARTICULARS

4.1.Therapeutic indications

Emergency contraception within 72 hours after an unprotected sexual intercourse or in case of failureof a contraceptive method.

4.2.Posology and method of administrationFor oral administration:

One tablet should be taken as soon as possible, preferably within 12 hours, and no later than 72 hoursafter unprotected intercourse (see section 5.1).

If vomiting occurs within three hours of taking the tablet, another tablet should be taken immediately. Trust Daisy 1 EC tablets can be used at any time during the menstrual cycle unless menstrual bleedingis overdue.

After using emergency contraception, it is recommended to use a local barrier method (e.g., condom, diaphragm, spermicide, cervical cap) until the next menstrual period starts. The use of levonorgestrel does not contraindicate the continuation of regular hormonal contraception.

Paediatric population

Trust Daisy 1 EC tablets are not recommended in children. Very limited data are available in women under 16 years of age.

4.3.Contraindications

Trust Daisy 1 EC (Levonorgestrel 1.5mg tablets) is contraindicated in patients with known hypersensitivity to Trust Daisy 1 EC or any of its excipients.

4.4.Special warnings and precautions for use

Emergency contraception is an occasional method. It should in no instance replace a regular contraceptive method.
Emergency contraception does not prevent a pregnancy in every instance. 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 Trust Daisy 1 EC 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 excluded. If pregnancy occurs after treatment with Trust Daisy 1 EC, the possibility of an ectopic pregnancy should be considered. The absolute risk of ectopic pregnancy is likely to be low, as Trust Daisy 1 EC prevents ovulation and fertilization. Ectopic pregnancy may continue, despite the occurrence of uterine bleeding.
Therefore, Trust Daisy 1 EC is not recommended for patients who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy).
Trust Daisy 1 EC is not recommended in patients with severe hepatic dysfunction.

Severe malabsorption syndromes, such as Crohn's disease, might impair the efficacy of Trust Daisy 1 EC.
This medicinal product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not takethis medicine.
After Trust Daisy 1 EC intake, 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 make a medical appointment to initiate or adopt a method of regular contraception. If no withdrawal bleed occurs in the next pill-free period following the use of Trust Daisy 1 EC after regular hormonal contraception, pregnancy should be ruled out.
Repeated administration within a menstrual cycle is not advisable because of the possibility of disturbance of the cycle.

Limited and inconclusive data suggest that there may be reduced efficacy of Trust Daisy 1 EC with increasing body weight or body mass index (BMI) (see section 5.1). In all women, emergency contraception should be taken as soon as possible after unprotected intercourse, regardless of the woman's body weight or BMI.

Trust Daisy 1 EC 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.

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.

Drugs suspected of having the capacity to reduce the efficacy of levonorgestrel include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin.

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

4.6.Fertility, pregnancy and lactation

Pregnancy
Levonorgestrel should not be given to pregnant women. It will not interrupt a pregnancy. In the caseof continued pregnancy, limited epidemiological data indicate no adverse effects on the fetus but thereare no clinical data on the potential consequences if doses greater than 1.5 mg of levonorgestrel are taken.

Breast-feeding
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 atleast 8 hours following Levonorgestrel administration.

Fertility

Levonorgestrel increases the possibility of cycle disturbances which can sometimes lead to earlier orlater ovulation date. These changes can result in modified fertility date; however, there are no fertility data in the long term.

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

Undesirable effects which have been observed are:

- nausea and vomiting
- dizziness, fatigue, headache
- abdominal pain
- a feeling of breast tenderness
- bleeding can occur after taking this medicine.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to **TMDA.**

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 - G03AD01

Mechanism of action

The precise mode of action of Trust Daisy 1 EC is not known

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

Efficacy: It has been estimated that levonorgestrel emergency contraceptive pills prevent 85% ofexpected pregnancies. Efficacy appears to decline with time after intercourse (95% within 24

hours, 85% if used between 24 and 48 hours, 58% if used between 48 and 72 hours).

It is therefore, recommended that the course of Trust Daisy 1 EC tablets is started 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 drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. 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%).

5.3.2 Pharmacokinetic Properties

Absorption
Orally administered levonorgestrel is rapidly and almost completely absorbed.

Distribution

The results of a pharmacokinetic study carried out with 16 healthy women showed that following ingestion of single dose of 1.5 mg levonorgestrel maximum drug serum levels of levonorgestrel of 18.5 ng/ml were found at 2 hours. After reaching maximum serum levels, the concentration of levonorgestrel decreased with a mean elimination half-life of about 26 hours.

Biotransformation

Levonorgestrel is not excreted in unchanged form but as metabolites.

Elimination

Levonorgestrel metabolites are excreted in about equal proportions with 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.

5.3 Preclinical safety data

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

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeat-dose toxicity, genotoxicity and carcinogenicity potential, beyond the information included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1.List of Excipients

Starch, Pre-gelatinized (1500)
Maize Starch
Povidone (K-30)
Magnesium Stearate
Silica, Colloidal Anhydrous
Lactose Monohydrate
Ethanol

6.2.Incompatibilities

Not Applicable.

6.3.Shelf life

Four (4) years from the date of manufacturing.

6.4.Special precautions for storage

Do not store above 30^{o}C. Store in the original package in order to protect from the moisture.

6.5.Nature and contents of container

PVC-Alu blister pack contains 1 uncoated tablet and IFC contains 1 blister pack.

6.6. Special precautions for disposal and other handling

No special requirements.

1. MARKETING AUTHORISATION HOLDER

Renata Limited
Section-7, Milk Vita Road,
Dhaka-1216, Bangladesh

8. MARKETING AUTHORISATION NUMBER

TAN 22 HM 0433

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07th October, 2022

10. DATE OF REVISION OF THE TEXT