SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Proctodar® Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Proctodar® Ointment: Tube of 15 grams. Each gram contains 20.0 mg Lidocaine Hydrochloride and 0.1 mg Fluocinolone Acetonide.

Excipients with known effect
Each 1 gram of this medicinal product contains 70 mg Cetyl Alcohol, 0.5 mg Propylparaben,1.7 mg Methylparaben and 100 mg Propylene Glycol.

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Ointment.

Proctodar® is white homogeneous ointment

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

External and internal haemorrhoids, anal eczema, proctitis, anal pruritus, pre-and postoperative treatment.

Proctodar® is indicated for the symptomatic treatment of inflammation and pruritus (itching) in skin diseases responsive to topical corticosteroids, such as external and internal haemorrhoids, perianal eczema, itching around the anus and other pathological conditions of the rectoanal region.

Prescription only medicine

4.2. Posology and method of administration

Before using Proctodar® Ointment and after defecation the anal region must be carefully washed with warm and a soft disposable cloth, if possible without soap. Proctodar® Ointment is to be applied twice or three times daily and gently smoothed in. The ointment can be applied intrarectally by means of the applicator enclosed in the pack.

Duration of administration

The duration of treatment depends on the symptoms or feelings and usually does not exceed 2-3 weeks. If longer treatment is necessary, the physician should check the patient's condition and decide whether or not to continue or repeat treatment. Infants, toddlers and children: No special studies have been carried out on paediatric.

4.3. Contraindications

Proctodar® Ointment must not be applied to areas affected by tubercular, syphilitic, bacterial, fungal or viral diseases. On known intolerance to one of the component of the ointment, or on the occurrence of intolerance during treatment, the respective formulation must not be used or it must be discontinued. Infants and toddlers are not to be treated with Proctodar® Ointment, as sufficient experience on application is not yet available in this age group.

4.4. Special warnings and precautions for use

In order to ensure the greatest possible therapeutic safety, long-term treatment and application to large areas, particularly under occlusion, should be avoided, if possible, in patients in whom systemic corticoid treatment is contraindicated or must be carried out with special care. If it is carried out, the precautions applying to systemic corticoid treatment should be taken. If possible, the product should not be applied continuously for more than 2-3 weeks.

Corticosteroids may mask symptoms of an allergic reaction to a component of the product. Patient should be advised that the product is only to be used for their particular disease and is not to be passed on to other people. As with all strong fluorinated corticosteroids, care is necessary when applying Proctodar® to the genital region and treatment should not be carried out for more than one week. Like all corticosteroids long term application may lead to dermal or mucosal therapy.

Proctodar® ointment contains:

- Cetyl alcohol and Stearyl alcohol: may cause local skin reactions (e.g. contactdermatitis).
- Methyl and propylparaben: may cause allergic reactions (possibly delayed).
- Propylene glycol: may cause skin irritation.

4.5. Interaction with other medicinal products and other forms of interaction

During treatment with Proctodar® Ointment the excipient paraffin may diminish the strength of latex condoms used at the same time, thus affecting their reliability.

4.6. Pregnancy and lactation

Animal studies have shown evidence of embryotoxicity and foetoxicity (in particular cleft palate). Human studies have so far not shown any such effects, but intra-uterine growth disorders cannot be ruled out on long-term treatment. The medicinal product must not be used during pregnancy, unless absolutely necessary. During pregnancy it should not be applied to large areas, in large quantities or for long periods. Glucocorticoids and lidocaine hydrochloride pass into the breast milk. Therefore, breastfeeding should not take place during long-term therapy or on treatment of large areas of the body.

4.7. Effects on ability to drive and use machines

Effects on road safety and the operation of machinery have not been investigated.

4.8. Undesirable effects

Skin
Rare (≥0.01% -<0.1%)

Initially brief smarting may occur. In rare cases irritation, pruritus, hypersensitivity reactions, such as allergic dermal reactions and pyrexia, and secondary infections may occur. On long-term treatment with Proctodar® Ointment dermal atrophy in the application area cannot be ruled out.

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

An overdose may increase in the incidence of the manifestations mentioned under "undesirable effects".

5. PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

ATC code C05AA10

Fluocinolone Acetonide, the topical corticosteroids in Proctodar® Ointment, has a pronounced anti-inflammatory, anti-allergic, antipruritic and anti-exudative effect. Topical corticosteroids are divided into four groups- very strong, strong, moderate and weak- and Proctodar® Ointment is a moderate topical corticosteroids preparation.

On topical application lidocaine has local analgesic and anaesthetic effects.

5.1. Pharmacokinetic properties

Pharmacokinetic investigations on the active substance combination like the composition in Proctodar® Ointment have so far not been carried out. It is, however, known that the degree of cutaneous corticosteroid absorption mainly depends on the mode of application, such as open treatment or under an occlusive dressing, the area treated, the moisture content, and in particular, the condition of the skin. In healthy volunteers treated for three weeks with 15 mg fluocinolone acetonide cream (0.025%)daily, applied to about 1200 cm^2 of dorsal skin, there was a mean reduction in urinary excretion of 17-ketosteroids of up to 1.3%. consequently, the systemic effect of topical fluocinolone acetonide is negligible when used according to instructions.

Kinetics in special patient's groups.

As regards use in infant and toddlers, see "contraindications"

5.2. Preclinical safety data

Animal experiments with systemic corticosteroids have shown a teratogenic potential (in particular cleft palate).

Tests on the mutagenicity and systemic carcinogenicity of fluocinolone acetonidehave not been carried out.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Cetyl alcohol, Stearyl alcohol, liquid paraffin, Polysorbate 20, sorbitan monostearate, citric acid, propyl hydroxybenzoate, methyl hydroxybenzoate, white soft paraffin, propylene glycol and purified water.

6.2. Incompatibilities

None known.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store below 30°C.
Discard unused content 30 days after first breaking the tube seal.

6.5. Nature and contents of container

Collapsible aluminum tube available in a carton box with a leaflet and an applicatorwith a cap

6.6. Special precautions for disposal and other handling

Medicines should not be disposed of via wastewater or household waste.

7. MARKETING AUTHORISATION HOLDER

Dar Al Dawa Development & Investment Co. Ltd.
Na'ur – Jordan
P.O. Box 9364 Amman - Jordan

8. MARKETING AUTHORISATION NUMBER(S)

TAN 22 HM 0493

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05th December, 2022

10. DATE OF REVISION OF THE TEXT