Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Perinal Cutaneous Spray hydrocortisone 0.2% w/w / lidocaine hydrochloride monohydrate 1.0% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrocortisone 0.2% w/w
Lidocaine hydrochloride monohydrate 1.0% w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Spray, Solution. (Cutaneous Spray)

Colourless to pale yellow aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Perinal is indicated for the symptomatic relief of anal and perianal itch, irritation and pain, such as associated with haemorrhoids.
Perinal is indicated in adults, children and adolescents.
Use in children under 14 years is recommended only under medical supervision (see section 4.2).

4.2 Posology and method of administration

Prime the pump before initial use by depressing it once or twice.

Spray once over the affected area up to three times daily, depending on the severity of the condition, or as recommended by the doctor.

The same dosage schedule applies to all age groups.

Paediatric population
Perinal is indicated in the paediatric population however special care should be exercised before treating children and adolescents aged under 14 years, to exclude any other underlying medical conditions.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients in section 6.1.
Not to be used on broken skin owing to the possibly increased risk of systemic side effects (see section 4.9).
Not to be used on infected skin including bacterial, viral, tuberculous or fungal lesions of the skin.
Not to be used internally (inside the anus), or anywhere other than the anal area.

4.4 Special warnings and precautions for use

Perinal Cutaneous Spray is intended for use for limited periods and so should not be used continuously for longer than 7 days without medical advice. Patients should be instructed to seek medical advice if they experience persistent pain or bleeding from the anus, especially where associated with a change in bowel habit, if the stomach is distended or if they are losing weight. Prompt medical treatment may be very important under such circumstances.
Medical supervision is required if used in conjunction with other medicines containing steroids, owing to possible additive effects.

Avoid prolonged, excessive use as this may produce local atrophy of the skin, striae or systemic corticosteroid effects such as suppression of adrenocortical function.

Visual disturbance
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Perinal Cutaneous Spray should not be ingested or applied into the mouth, inside the nose or in the eyes.

4.5 Interaction with other medicinal products and other forms of interactions

Due to possible lidocaine additive effects, Perinal Cutaneous Spray should be used with caution in patients taking Class III antiarrhythmic drugs (such as amiodarone), or other local anaesthetics at the same time.
Medicinal products that reduce the clearance of lidocaine (e.g. cimetidine or betablockers) may increase the risk of overdose (see section 4.9), although the risk is considered very low for Perinal Cutaneous Spray owing to the low doses applied.

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in the human foetus. Perinal Cutaneous Spray should only be used during pregnancy if the patient's physician considers that the potential benefits outweigh the potential risks to the foetus.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

A temporary tingling sensation may be experienced locally after initial application. There have been rare reports of hypersensitivity to lidocaine.

Eye disorders
Not known (frequency cannot be estimated from the available data): Vision, blurred (see also section 4.4).

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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Under exceptional circumstances, if Perinal Cutaneous Spray is used excessively, particularly in young children, it is theoretically possible that adrenal suppression and skin thinning may occur. The symptoms are normally reversible on cessation of treatment.
Overdose may cause systemic side effects such as nervous system excitation and, in severe cases, central nervous and cardiovascular depression.
In case of suspected overdose, discontinue use of this product and seek urgent medical attention.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihemorrhoidals for topical use (products containing corticosteroids), ATC code: C05A A.

The preparation combines the well-known local anti-inflammatory and antipruritic properties of hydrocortisone and the analgesic effect of lidocaine in an aqueous spray formulation.

5.2 Pharmacokinetic properties

The active ingredients of the formulation are readily available for intimate contact with the skin and mucous membranes, as the preparation is sprayed in small droplets which dry after application to leave the active ingredients in close contact with the affected area.

5.3 Preclinical safety data

No special information.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol cetostearyl ether (Cetomacrogol)
Citric acid monohydrate
Phenoxyethanol
Sodium citrate
Propyl gallate
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

30 ml high density polyethylene aluminium/EAA copolymer collapsible laminate tube with spray pump (precitube) and cap.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Dermal Laboratories (Ireland) Limited
38 Main Street
Swords
Co Dublin
K67 E0A2
Ireland

8 MARKETING AUTHORISATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5 June 1992

Date of last renewal: 5 June 2007

10 DATE OF REVISION OF THE TEXT

December 2020