Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Prednisolone 20 mg Rectal Foam

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains 31.4 mg of the active ingredient prednisolone metasulphobenzoate sodium, equivalent to prednisolone 20.0 mg
Excipients with known effect: Cetostearyl alcohol 4.4 mg, Sorbic Acid 1.74 mg, and Polysorbate 20 43.7 mg per dose.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Rectal Foam

A white to pale cream coloured, metered-dose rectal foam.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of proctitis and ulcerative colitis.

4.2 Posology and method of administration

Posology

Adults and elderly patients:

One metered dose rectally once or twice daily for 2 weeks, extending treatment for a further 2 weeks when a good response is obtained. Use should be discontinued at the discretion of the physician once the disease is stable and under control.

Paediatric population:
Not recommended.

Shake canister before use. When using for the first time remove and discard the small plastic safety tag from under the button. An applicator nozzle is then pushed onto the side arm of the canister. The semi-circular cut-out on the cap is lined up with the nozzle. The easiest way to administer Prednisolone 20 mg Rectal Foam is to stand with one foot raised on a chair and gently insert the nozzle tip into the rectum.

Smearing the nozzle with lubricating jelly may help insertion. Holding the canister with the dose button pointing down, press the button on the canister firmly and release. Only press the button once so as not to exceed the recommended dose.

Method of administration:

For rectal administration only.

4.3 Contraindications

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

Local conditions where infection might be masked or healing impaired, e.g. peritonitis, fistulae, intestinal obstruction, perforation of the bowel.

4.4 Special warnings and precautions for use

This product should be used with extreme caution in the presence of severe ulcerative colitis. The possibility of masking local or systemic infection should be borne in mind when using this product.

Scleroderma renal crisis

Caution is required in patients with systemic sclerosis because of an increased incidence of (possibly fatal) scleroderma renal crisis with hypertension and decreased urinary output observed with a daily dose of 15 mg or more prednisolone. Blood pressure and renal function (s-creatinine) should therefore be routinely checked. When renal crisis is suspected, blood pressure should be carefully controlled.

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.

Excipients

This medicinal product contains cetostearyl alcohol and sorbic acid which may cause local skin reactions, (e.g. contact dermatitis).

This medicinal product contains Polysorbates which can cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions have been reported between corticosteroids and non-steroidal anti-inflammatory drugs, barbiturates, diuretics, phenytoin, rifampicin, amphotericin, anticoagulants, cyclophosphamide, hypoglycaemic agents and vaccines. These are all well known and documented interactions.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

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 in foetal development including cleft palate and intrauterine growth retardation. There may therefore be a very small risk of such effects in the human foetus.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The consequences of systemic absorption should be considered with extensive use over prolonged periods. As with all rectal corticosteroids, prolonged continuous use is undesirable.

Frequency 'not known': Scleroderma renal crisis*, bradycardia**

*see section c)

**following high doses

c) Scleroderma renal crisis

Amongst the different subpopulations the occurrence of scleroderma renal crisis varies. The highest risk has been reported in patients with diffuse systemic sclerosis. The lowest risk has been reported in patients with limited systemic sclerosis (2%) and juvenile onset systemic sclerosis (1%).

Eye disorders

Not known: 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

Overdosage by this route is unlikely.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Corticosteroids for local use
ATC code: A07EA01

Prednisolone is a semi-synthetic analogue of cortisol, with slightly less mineralcorticoid activity but about four times the anti-inflammatory activity. Prednisolone produces less sodium and water retention and potassium loss than cortisol. In order to obtain local corticosteroid activity in the lower part of the colon prednisolone may be administered as an enema. The half life of prednisolone is 2.5 to 3 hours and it is bound to transcortin (corticosteroid binding globulin, CBG). Systemic absorption may occur following administration into the rectum, but is less with this salt.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetomacrogol emulsifying wax
Cetostearyl alcohol
Oleyl alcohol
Light liquid paraffin
Phenoxyethanol
Sorbic acid
Polysorbate 20
Disodium edetate
Sodium hydroxide
Purified water
Butane 48 (propane, iso-butane, n-butane)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Pressurised container containing a flammable propellant. Do not store above 25°C. Protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn even after use. Do not spray on naked flame or any incandescent material.

6.5 Nature and contents of container

Each pack contains an aluminium aerosol can fitted with a metering valve containing sufficient for 14 doses plus 14 disposable applicators.

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

Chemidex Pharma Limited
Vision Exchange Building
Triq it-Territorjals, Zone 1
Central Business District
Birkirkara
CBD 1070
Malta

8 MARKETING AUTHORISATION NUMBER

PA22643/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 November 1989

Date of last renewal: 28 November 2009

10 DATE OF REVISION OF THE TEXT

December 2025