

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Prednisolone 20 mg Rectal Foam

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains 31.4mg of the active ingredient prednisolone metasulphobenzoate sodium, equivalent to prednisolone 20.0mg

Excipients with known effect: Cetostearyl alcohol 4.4mg and Sorbic Acid 1.74mg

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 15mg 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.

##### Excipients

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

#### 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%).

#### 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

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#### **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**

15 months

#### **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**

April 2023