

**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

**MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007**

**(S.I. No.540 of 2007)**

**PA1161/005/001**

Case No: 2045535

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Transferred from PA0100/007/001.

**Chemidex Pharma Limited T/A Essential Generics**

**Chemidex House, Egham Business Village, Crabtree Road, Egham, Surrey TW20 8RB, United Kingdom**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

**Predenema 20 mg/100 ml Rectal Solution**

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **06/02/2009**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE MEDICINAL PRODUCT

Predenema 20 mg/ 100 ml Rectal Solution

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100ml unit contains prednisolone sodium metasulphobenzoate equivalent to 20 mg of prednisolone.

Excipients: Each 100ml contains 55mg methyl hydroxybenzoate, 15.5mg ethyl hydroxybenzoate, 7.5mg propyl hydroxybenzoate, 7.5mg iso-butyl hydroxybenzoate and 14.5mg butyl hydroxybenzoate.

For a full list of excipients, see section 6.1

#### 3 PHARMACEUTICAL FORM

Rectal solution.

Single dose disposable enema unit containing a clear to slightly hazy solution.

#### 4 CLINICAL PARTICULARS

##### 4.1 Therapeutic Indications

In the local management of distal ulcerative colitis.

##### 4.2 Posology and method of administration

###### Adults

Intrarectal. The contents of a single unit daily before retiring for two to four weeks or as directed by the physician.

Before use the patient should lie in bed on their side with knees drawn up. The enema may be administered at room temperature or warmed in warm water before use.

Bag enema: Hold the bag with tube upwards, squeeze base of tube where it joins the bag.

Remove cap and lubricate tube before insertion into rectum. Squeeze gently until fluid is dispelled and discard bag hygienically.

Bottle enema: Keeping bottle upright, remove blue protective cap. Insert nozzle into rectum and squeeze bottle gently until fluid is dispelled. Discard bottle hygienically. For the 'long-tube' version first carefully remove the bottle cap, screw on the applicator and then administer as above.

After administration the patient should lie face down for a few minutes to retain the fluid before going to sleep in their usual position.

###### Children

Not recommended.

### **4.3 Contraindications**

Use during remissions of the disease.

Use in presence of lower intestinal obstruction, local abscess, fistulae or sinuses or penetrating or advanced ulcerative lesions carrying a hazard of perforation.

Hypersensitivity to the preparation.

Use in untreated infection by viruses or other micro-organisms.

### **4.4 Special warnings and precautions for use**

The consequences of systemic absorption (e.g. suppression of the HPA axis), should be considered if Predenema is used over long periods or in high dosage.

Systemic absorption of corticosteroid may occur with consequent production of signs of excessive hormone levels. Prolonged use will render this more likely.

The product should only be used with extreme caution in the presence of severe ulcerative disease.

The possibility of local or systemic infection should be borne in mind when using this product, particularly in view of the possible absence of systemic response thereto.

There have been a few reports in the literature of the development of cataracts in patients who have been using corticosteroids for prolonged periods of time. Although it is not possible to rule out systemic corticosteroids as a known factor, prescribers should be aware of the possible role of corticosteroids in cataract development.

### **4.5 Interaction with other medicinal products and other forms of interaction**

None known

### **4.6 Pregnancy and lactation**

Topical administration of corticosteroids to pregnant animals can cause abnormalities in foetal development. The relevance of this finding to human beings has not been established; however, topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for prolonged periods.

### **4.7 Effects on ability to drive and use machines**

None stated

### **4.8 Undesirable effects**

None stated

### **4.9 Overdose**

Overdose by this route is unlikely

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Prednisolone 21-sodium metasulphobenzoate has the general properties of prednisolone as a potent anti-inflammatory agent with immuno-suppressant glucocorticoid properties. Esterification of prednisolone at the 21 position increases the topical activity of the drug.

### 5.2 Pharmacokinetic properties

Following rectal administration of prednisolone 21-sodium metasulphobenzoate in the form of an enema, the action of the drug is predominantly local. The peak plasma levels obtained following this treatment are significantly lower than those obtained following treatment with prednisolone 21-phosphate.

Following absorption, the drug is hydrolysed to m-sulphobenzoic acid (and salts) and free prednisolone.

At the low plasma levels obtained, following rectal administration of prednisolone 21-sodium metasulphobenzoate the precautions generally applied to the use of prednisolone are considered to be unnecessary.

### 5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber that might add to the safety data provided in other sections of this SPC.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Disodium Edetate

Nipastat containing:

Methyl hydroxybenzoate (E218)

Ethyl hydroxybenzoate (E214)

Butyl hydroxybenzoate

Propyl hydroxybenzoate (E216)

Iso-butyl hydroxybenzoate

Purified Water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf Life

Unopened: 1 Year

Once opened: For single use only, any unused content should be discarded.

### 6.4 Special precautions for storage

Do not store above 25°C. Store the bottles or bags in the outer carton.

## **6.5 Nature and contents of container**

### **Bottle**

Predenema is presented in a single-dose, disposable EVA (Polyethylene vinyl acetate) bottle containing 100ml of solution with a prelubricated PVC applicator. A version with a separate applicator and extension tube is available for those patients who may find it helpful. The standard presentation is packed singly in a carton. The long-tube version is supplied in packs of seven bottles and seven screw-on long tube applicators in a cardboard carton.

### **Bag**

Predenema is presented in a single-dose, disposable PVC enema bag containing 100ml of solution. The enema bag is contained in a clear polypropylene outer bag. It is available with a standard tube in packs of ten per carton or with an extension tube (long tube) in packs of seven per carton.

Not all presentations may be marketed.

## **6.6 Special precautions for disposal**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Chemidex Pharma Limited  
Chemidex House  
Egham Business Village  
Crabtree Road  
Egham  
Surrey  
TW20 8RB  
United Kingdom

## **8 MARKETING AUTHORISATION NUMBER**

PA 1161/5/1

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 1<sup>st</sup> April 1978

Date of last renewal: 1<sup>st</sup> April 2008

## **10 DATE OF REVISION OF THE TEXT**

February 2009