

**SUMMARY OF PRODUCT CHARACTERISTIC (SPC)**

## **1. NAME OF THE MEDICINAL PRODUCT**

**DEXIPAN**( Dexpanthenol 5 g/ 100 mg cream)

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 100 gm of the cream contains 5.0 gm dexpanthenol .

For the full list of excipients, see section 6.1

## **3. PHARMACEUTICAL FORM**

Topical Cream

Soft, smooth, white to off-white cream base free from agglomerates with lavender-rose odour.

## **4. CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

**Dexipan** cream is used for treating overstressed and irritated but intact skin associated with:

- Redness and sunburn
- Pressure marks
- Mild burn
- Rough areas of skin (e.g. on the hands, elbows or feet)

### **4.2 Posology and method of administration**

For cutaneous use only, which means it is applied directly to the affected area of skin.

#### **How to apply the cream**

- Apply **Dexipan** once to several times daily as required.

### **4.3 Contraindications**

Hypersensitivity to dexpanthenol, or to any of the other ingredients of the cream

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

**Dexipan** should be used with caution in the presence of any of the following health problems:

- Other illnesses
- Allergies
- Taking or externally applying any other medicines.

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

Being a topical preparation with local action, no drug interactions have been reported with its use.

### **4.6 Pregnancy and lactation**

Dexpanthenol cream may be used during pregnancy and lactation

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

None.

#### **4.8 Undesirable effects**

The following side effects may occur when using dexpanthenol cream. Side effects of dexpanthenol have only rarely been observed to date. Unusual skin reactions may occur.

**Healthcare professionals are asked to report any suspected adverse reactions via:**

**Pharmacovigilance and Medical Device Section**

**Drug Department - U.A.E M.O.H**

**Hotline: 80011111**

**Email: pv@mohap.gov.ae**

**P.O. Box: 1853 Dubai U.A.E.**

#### **4.9 Overdose**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Dexpanthenol, the active ingredient of **Dexipan**, is necessary for normal epithelial function, as it is rapidly converted in skin cells to pantothenic acid, which plays a part in both the formation and the regeneration of the skin.

#### **5.2 Pharmacokinetics properties**

Dexpanthenol is readily converted to pantothenic acid which is widely distributed into body tissues, mainly as coenzyme A.

#### **5.3 Preclinical safety data**

None

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

White soft Paraffin  
Cetostearyl Alcohol  
Lanolin Anhydrous  
Liquid Paraffin  
Propylene Glycol  
Methyl Paraben  
Propyl Paraben  
Tween 60  
Simethicone M30  
Lavender Oil  
Rose Oil (synthetic)  
Purified water

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

**Before Opening:** 24 months from the date of manufacture.

**After Opening:** one month

**6.4 Special precautions for storage**

Store below 30°C.

**6.5 Nature and contents of container**

20g cream in collapsible aluminium tube packed in a printed carton along with a leaflet.

50g cream in a spray pump plastic tube packed in a printed carton along with a leaflet.

**6.6 Special precautions for disposal and other handling**

Not applicable.

**7. MARKETING AUTHORISATION HOLDER**

**Gulf Pharmaceutical Industries - Julphar**

Digdaga, Airport Street.

Ras Al Khaimah - United Arab Emirates.

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**8. MARKETING AUTHORISATION NUMBER(S)**

08308/VAR/2023

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

Oct 3, 2023

**10. DATE OF REVISION OF THE TEXT**

December 2023