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**Propylene Glycol Cream**

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**1. Generic Name:**

Propylene Glycol

**2. Qualitative and quantitative composition:**

Each gram contains:

Propylene Glycol I.P..... 15 mg

Diazolidinyl Urea (Preservative)....1.5 mg  
in a cream base.

The excipients used are Lecithin, Magnesium Aluminium Silicate, Carbomer-934P, Glycerin, Sodium Hydroxide, Caprylic Capric Acid Triglyceride, Dimethicone, Squalane, Polyoxyl 40 Stearate, Stearic acid, Glycol Stearate, Glyceryl Stearate, Cetyl Alcohol, Myristyl Myristate, Carboxylic Acid Sterol Ester, Butylated Hydroxytoluene, Tetrasodium Edetate Tetra hydrate, Diazolidinyl Urea and Purified Water.

**3. Dosage form and strength:**

**Dosage form:** Cream

**Strength:** 15 mg

**4. Clinical particulars:**

**4.1 Therapeutic indication:**

- Mild to severe dry skin as seen in Xerosis, Dry eczema, senile dry skin, ichthyosis, neurodermatitis and pruritis
- Adjuvant therapy in atopic eczema

**4.2 Posology and method of administration:**

Apply to the affected area twice a day after bathing or washing and rub in gently and thoroughly for full penetration. For external use only.

**4.3 Contraindications:**

Propylene glycol cream is contraindicated in the patients who are hypersensitive to Lecithin or to any ingredient in the formulation.

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

If irritation or sensitization develops with the use of propylene glycol cream, treatment should be discontinued and appropriate therapy instituted. Propylene glycol cream is not for ophthalmic use.

**4.5 Drug-Interaction:**

No information available.

**4.6 Use in special populations**

No information available.

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

No information available.

#### 4.8 Undesirable effects:

Phospholipids can be used safely and effectively with no side effects. However in some individuals burning, stinging, redness or irritation may occur. If any of these persists or worsens, physician should be consulted. Serious allergic reactions are very rare. If any symptoms of serious allergic reaction are noted, it warrants immediate medical attention.

##### Reporting of side effects:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

[http://www.torrentpharma.com/Index.php/site/info/adverse\\_event\\_reporting](http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting).

#### 4.9 Overdose:

No information available.

### 5. Pharmacological properties:

#### 5.1 Mechanism of Action:

No information available.

#### 5.2 Pharmacodynamic properties:

No information available.

#### 5.3 Pharmacokinetic properties:

No information available.

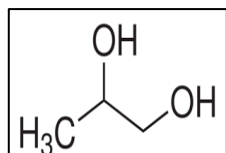
### 6. Nonclinical properties:

#### 6.1 Animal Toxicology or Pharmacology

No information available.

### 7. Description:

Propylene Glycol is chemically, propane-1,2-diol with molecular weight of 76.09 g/mol and molecular formula is [C<sub>3</sub>H<sub>8</sub>O<sub>2</sub>](#). The chemical structure is:



Propylene Glycol cream is a white, smooth, homogenous cream, free from foreign matter. The ingredients are Lecithin, Magnesium Aluminium Silicate, Carbomer-934P, Glycerin, Sodium Hydroxide, Caprylic Capric Acid Triglyceride, Dimethicone, Squalane, Polyoxyl 40 Stearate, Stearic acid, Glycol Stearate, Glyceryl Stearate, Cetyl Alcohol, Myristyl Myristate, Carboxylic Acid Sterol Ester, Butylated Hydroxytoluene, Tetrasodium Edetate Tetra hydrate, Diazolidinyl Urea and Purified Water.

## **8. Pharmaceutical particulars:**

### **8.1 Incompatibilities:**

Not applicable.

### **8.2 Shelf-life:**

Do not use later than the date of expiry.

### **8.3 Packaging information:**

Propylene glycol cream is available as 100g tube pack.

### **8.4 Storage and handing instructions:**

Store between 8° and 25°C. Do not freeze.

Keep out of reach of children.

## **9. Patient Counselling Information**

### **Package leaflet: Information for the user** Propylene Glycol Cream

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet?**

9.1 What Propylene glycol cream is and what it is used for

9.2 What you need to know before you use Propylene glycol cream

9.3 How to use Propylene glycol cream

9.4 Possible side effects

9.5 How to store Propylene glycol cream

9.6 Contents of the pack and other information

### **9.1. What is and what it is used for**

The main ingredient is Propylene glycol.

Propylene glycol cream has humectant properties and is used similarly to glycerol in topical moisturizing preparations. Diazolidinyl urea is a preservative.

Propylene glycol cream is indicated in

- Mild to severe dry skin as seen in Xerosis, Dry eczema, senile dry skin, ichthyosis, neurodermatitis and pruritis
- Adjuvant therapy in atopic eczema

### **9.2. What you need to know before you use Propylene glycol cream**

**Do not take Propylene glycol cream if:**

- you are hypersensitive to Lecithin or to any ingredient in the formulation.

## **Warnings and precautions**

If irritation or sensitization develops with the use of Propylene glycol cream, treatment should be discontinued and appropriate therapy instituted.

Propylene glycol cream is not for ophthalmic use.

### **9.3. How to use Propylene glycol cream**

Apply to the affected area twice a day after bathing or washing and rub in gently and thoroughly for full penetration. For external use only.

### **9.4. Possible side effects**

In some of the individuals burning, stinging, redness or irritation may occur. If any of these persists or worsens, physician should be consulted. Serious allergic reactions are very rare. If any symptoms of serious allergic reaction are noted, it warrants immediate medical attention.

#### **Reporting of side effects:**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via any point of contact of Torrent Pharma available at:

[http://www.torrentpharma.com/Index.php/site/info/adverse\\_event\\_reporting](http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting)

### **9.5. How to store Propylene glycol cream**

Store between 8° and 25°C. Do not freeze.

Keep out of reach of children.

### **9.6. Contents of the pack and other information**

#### **What Propylene glycol cream contains**

The main ingredients is Propylene glycol.

The ingredients are Lecithin, Magnesium Aluminium Silicate, Carbomer-934P, Glycerin, Sodium Hydroxide, Caprylic Capric Acid Triglyceride, Dimethicone, Squalane, Polyoxyl 40 Stearate, Stearic acid, Glycol Stearate, Glyceryl Stearate, Cetyl Alcohol, Myristyl Myristate, Carboxylic Acid Sterol Ester, Butylated Hydroxytoluene, Tetrasodium Edetate Tetra hydrate, Diazolidinyl Urea and Purified Water.

### **10. Details of manufacturer**

Manufactured by:

Torrent Pharmaceuticals Ltd.

Plot No. 810, Sector-III, Industrial Area,

Pithampur, Dist. Dhar -454 775 (M.P.), India

### **11. Details of permission or licence number with date**

M.L. 25/10/96 issued on 02.07.2016

### **12. Date of revision**

NA

MARKETED BY



TORRENT PHARMACEUTICALS LTD.

**IN/ Propylene glycol cream 15 mg/NOV-20/01/PI**