

## **PATIENT INFORMATION LEAFLET (PIL)**

### **MILZOL PLUS (Triple Action Cream)**

Information for the user

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

#### **In this leaflet**

1. What Milzol Plus (Triple Action Cream) are and what they are used for
2. Before you use Milzol Plus Cream
3. How to use Milzol Plus Cream
4. Possible side effects
5. How to store Milzol Plus Cream
6. Further information

#### **1. What Milzol Plus cream are and what they are used for Clotrimazole, Betamethasone Dipropionate, Neomycin Sulfate Antifungal - Anti-inflammatory - Antibacterial**

##### **Composition :**

Clotrimazole USP 1.0% w/w

Betamethasone Dipropionate USP  
equivalent to Betamethasone 0.05% w/w

Neomycin Sulphate USP 0.5% w/w

Chlorocresol USP (As preservative) 0.1% w/w Cream base q.s

Betamethasone belongs to a group of medicines called topical corticosteroids which are used on the surface of the skin to reduce the redness and itchiness caused by certain skin problems. Clotrimazole is a topical anti-fungal medicine used to treat some fungal

infections of the skin. Neomycin, an antibiotic, is used to prevent or treat skin infections caused by bacteria. It is not effective against fungal or viral infections.

MILZOL PLUS is indicated for topical use in the treatment of a wide range of eczemas and other inflammatory and allergic infections of the skin caused by various bacteria / fungi. These conditions include contact dermatitis, follicular dermatitis, impetigo, intertrigo, eczematoid dermatitis, non specific pruritus etc

## **2. Before you use Milzol Plus Cream**

### **Do not use Milzol Plus Cream**

- if you are allergic to betamethasone dipropionate, clotrimazole and neomycin sulphate or any of the other ingredients of this medicine (listed in section 6).
- if your skin becomes irritated, or you develop an allergic reaction.
- on any other skin infections as it could make them worse, especially rosacea (a skin condition affecting the face), acne, dermatitis (skin inflammation) around the mouth, nappy rash or other skin infections.

### **Warnings and precautions**

If you have psoriasis, your doctor may want to review your treatment regularly. Contact your doctor if your psoriasis gets worse or you get raised bumps filled with pus under your skin.

Contact your doctor immediately if you, or your child, experience blurred vision or other visual disturbances.

Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids used on the skin, especially in infants and children.

If you use more than the correct amount of cream and/or use it for longer than is recommended, it can affect the levels of certain hormones in the body, particularly in infants and children.

In adults the changes in hormone levels may lead rarely to puffiness or rounding of the face, weakness, tiredness, and dizziness when standing or sitting down.

### **Children**

Do not use this medicine on children under 12 years of age unless advised by your doctor.

If you use more than the correct amount of cream and/or use it for longer than is recommended, it can affect your child's hormones. Rarely this may lead to:

- Delayed growth and development

- A moon face or rounding of the face
- A build-up of pressure around the brain which can produce
  - a bulging of the fontanelle (the soft spot in the top of the skull) in infants
  - a constant thumping headache
  - blurred vision or other visual disturbances

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **3. How to use Milzol Plus Cream**

After cleaning the affected area, a sufficient quantity of MILZOL PLUS should be applied to the affected area to form a thin even layer, two or three times daily. This treatment should be continued for several days after the disappearance of symptoms.

### **4. Possible side effects**

Skin atrophy or striae may occur following long term treatment with preparation containing corticosteroids.

### **5. How to store Milzol Plus Cream**

Store in a cool place protect from light. Do not freeze.

For external use only.

Keep the tube tightly closed.

### **6. Further information**

#### **What Milzol plus Cream contains**

The active substances are betamethasone dipropionate, Clotrimazole and Neomycin sulphate.

The other ingredients are:

Chlorocresol, Sodium Acid Phosphate, Propylene Glycol, Polysorbate-80, Paraffin Liquid light, Cetomacrogol-1000, Cetostearyl Alcohol

What Milzol Cream looks like and contents of the pack

White colored cream

What Milzol Plus Cream look like and contents of the pack

**MILAN LABORATORIES (INDIA) PVT. LTD.**

**MILZOL PLUS (Triple Action Cream)**



Presentation: Tube of 30 g

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