#### CORNEX- lactic acid, salicylic acid gel Pella Pharmaceuticals Co. Ltd

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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#### Cornex

## **Active Ingredients**

Each one gram contains: Lactic acid 167mg and salicylic acid 167mg.

#### Composition

Excipients: Alcohol, Hydroxypropyl Cellulose.

## **Properties**

Cornex is a topical gel for the removal of warts and corns.

#### **Indications**

Cornex is used to remove Warts and Corns. A wart is a viral infection of the skin surface layer. The incubation period varies from a few weeks to several months. Warts can be spread by contact of the virus with damaged skin, particularly if warm and moist. This is why one of the most common sources of infection is swimming pools. Corns are hard, thick pads of skin caused by pressure and friction. They usually occur on the feet due to poorly fitting shoes. They can also occur on hands. Cornex Gel is suitable for use by adults, children and the elderly.

#### **Contraindications**

Cornex is contraindicated in patients with known hypersensitivity to lactic acid and / or salicylic acid or to any other components of this product.

Do not use Cornex if you are diabetic or suffer from poor blood circulation to your hands or feet.

#### **Precautions**

Cornex is formulated for the controlled corrosion of keratin and thus care should be taken to apply the product to the wart only. Avoid applying it to normal surrounding skin. Do not use Cornex on the face, mucous membranes or anogenital reagions. Cornex is not recommended for use in infants under 2 years of age. Children under 12 years should only use the product under supervision.

#### **Precaution**

As well all the medicines you should keep Cornex out of reach of children.

## **Drug Interactions**

No interaction betyween Lactic acid and Salicylic acid and other drugs or substances are known or suspected.

#### **Warnings**

Remember that warts are infectious. To prevent the infection spreading to others always keep to your own towel. Do not walk about barefoot if warts are on the soles of your feet. Be patient, it can take 6 to 12 weeks to completely remove the wart. Do not use Cornex on moles, brithmarks or unusual skin growths or near eyes or on mucous membranes.

Avoid use on broken or inflamed skin.

## **Dosage and Administration**

Remove any plaster and soak the wart in hot water for five minutes. Dry with your own towel. Rub the surface of the warts carefully with a pumice stone or emery board. Apply Cornex daily to the warts. Use only enough Cornex to cover the warts and avoid applying to the surrounding normal skin.

Allow Cornex to dry and cover with plaster if the wart is large or on foot. Continue using Cemex daily until the wart is completely cleared and the ridge lines of the skin have been restored.

#### Side Effects

Avoid use on large areas of skin; as this may result in absorption of sufficient quantities to cause adverse effects.

# Storage

Store below 30 "C.

# How supplied

15 g packs.

# **Secondary Package**



# **Primary Package**



Topical gel for the removal of warts & corns

- EACH 1G CONTAINS:
  Lactic Acid (167mg)
- Salicylic Acid (167mg)

#### DIRECTIONS:

For method of application, read the enclosed leaflet



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Store below 30 °C. Read enclosed leaflet before use. Keep out of reach of children.

FOR TOPICAL USE ONLY

# **CORNEX**

lactic acid, salicylic acid gel

#### **Product Information**

**Product Type** HUMAN OTC DRUG **Item Code (Source)** NDC:82160-238

**Route of Administration TOPICAL** 

# **Active Ingredient/Active Moiety**

Ingredient Name	<b>Basis of Strength</b>	Strength
LACTIC ACID (UNII: 33X04XA5AT) (LACTIC ACID - UNII:33X04XA5AT)	LACTIC ACID	2505 mg in 15 g
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2505 mg in 15 g

# **Inactive Ingredients**

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ 8H6N6OH)	

# **Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82160-238- 01	1 in 1 CARTON	03/25/2010	
1		15 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M030	03/25/2010		

# Labeler - Pella Pharmaceuticals Co. Ltd (562370925)

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