DERMA WOUND-EAZ- cetrimide cream
Pella Pharmaceuticals Co. Ltd

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Wound-Eaz

Form and Presentation

Cream: Laminated Tube, 25 g

Active Ingredient

Cetrimide

Inactive Ingredients

Aqua, Paraffinium Liquidium, Cetearyl Alcohol, Petrolatum, Phenyl Trimethicone, Ceteareth-20, Benzyl Alcohol, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Hyaluronic Acid, Triethanolamine, Chlorhexidine Digluconate, Disodium EDTA.

Purpose

Wound and scars care cream

Properties

This product is for the management of wounds and scars, it provides deep skin hydration, accelerates the process of regeneration. It works by softening and flattening raised scars of any kind and is an effective antiseptic with a wide range of activity against micro-organisms, including gram-positive and gram-negative bacteria, fungi, and viruses.

Indications

Used for the disinfection and healing of the wounds and burns and to reduce the appearance of scars that result from cuts and grazes, also used for dermatological disorders such as insect bites and stings, minor burns and scalds, sunburn, blisters and sores.

Precaution

Keep out of reach of children

Warnings

- For external use only.
- Avoid contact with eyes, if accidentally splashed into the eye, the open eye should be irrigated for at least 10 minutes.
- Discontinue use if irritation (redness, pain, etc.) occurs. If skin irritation occurs, consult your physician if the symptoms persist for more than 48 hr.

Contraindications

Hypersensitivity to any of the components.

Side Effects

Skin irritation.

Pregnancy and Lactation

There are no adequate data from the use of chlorhexidine digluconate and cetrimide in pregnant women.

The potential risk for humans is unknown but is most likely very low since chlorhexidine digluconate and cetrimide are poorly absorbed following topical application.

It is not known whether chlorhexidine digluconate and cetrimide are excreted in breast milk. There are no adequate data from the use of chlorhexidine and cetrimide in breastfeeding women. However, it is unlikely that the products are excreted in breast milk since the products are poorly absorbed. After topical usage of the product, as a general precaution, rinse nipples thoroughly with water before breastfeeding.

Dosage and Administration

With a clean hand gently apply the cream to the affected area in a layer of about 2 to 3 mm thickness or place the cream on sterile gauze and then apply it to the wound.

Apply the cream 2 to 3 times a day or as prescribed by the doctor and the duration of use depends on the improvement of the symptoms.

Interactions

The product is incompatible with anionic substances (e.g. soap, toothpaste).

Storage Conditions

Store below 30 °C

Primary Package

Secondary Package

Outside

DERMA WOUND-EAZ

cetrimide cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:82160-696
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CETRIMIDE (UNII: 24QSH2NL8N) (CETRIMIDE - UNII:24QSH2NL8N)	CETRIMIDE	5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
TROLAMINE (UNII: 9O3K93S3TK)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
PETROLATUM (UNII: 4T6H12BN9U)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82160-696-01	1 in 1 CARTON	10/31/2022	
1		25 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
unapproved drug other		10/31/2022	

Labeler - Pella Pharmaceuticals Co. Ltd (562370925)

Revised: 6/2023 Pella Pharmaceuticals Co. Ltd