GENGICURE- hyaluronic acid gel 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.

Gengicure

Forms and Presentation

Gel: Tube 15 g

Active Ingredient

Hyaluronic Acid

Inactive Ingredients

Aqua, Hydroxypropyl Cellulose, Sodium Benzoate and Dichlorobenzyl Alcohol.

Purpose

Helps healing internal and external mouth ulcers and relieving pain

Properties

gengicure® gel has a special formula immediately reduces pain and promotes the treatment of oral mucosal ulcers by accelerating normal healing process because it contains hyaluronic acid, a natural substance found in the connective tissues of the body. When applied to the ulcers it stimulates the production of new healthy tissue. Paraben Free

Sugar Free

Colorants Free

Indication

gengicure ®gel helps healing internal and external mouth ulcers and relieving pain

Precautions

Keep out of reach of children

Warnings

• Do not swallow the product

• If symptoms persist consult your doctor

Contraindication

- Hypersensitivity to any of the components
- Do not use for children under 2 years

Pregnancy and Lactation

Ask your doctor or pharmacist for advice before using any product.

If you want to apply the gel during pregnancy or lactation then discuss this with your doctor

Interactions

No interactions between gengicure [®] gel and other drugs or substances are known or suspected.

Side effects

There are no known side effects

Dosage and administration

Apply a film of gel onto affected area only, massaging gently with clean fingers to aid its correct distribution and then keep it to dry for 30 – 60 seconds.

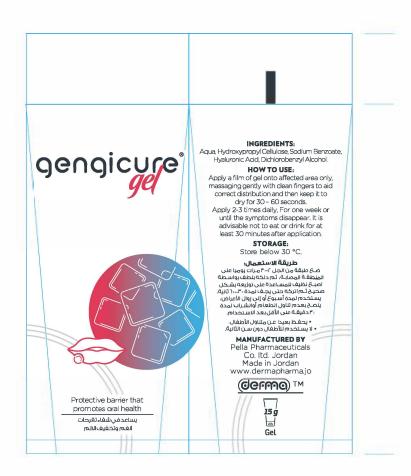
Apply 2-3 times daily, for one week or until the symptoms disappear.

It is advisable not to eat or drink for at least 30 minutes after application.

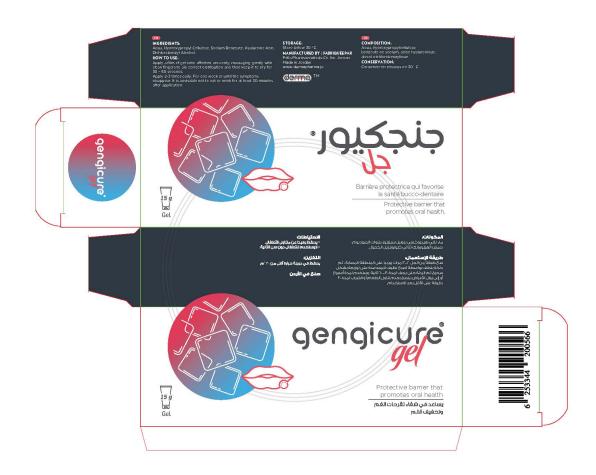
Storage Conditions

Store below 30 °C.

Primary Package



Secondary Package



GENGICURE

hyaluronic acid gel

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82160-566

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYALURONIC ACID (UNII: S270N0TRQY) (HYALURONIC ACID - UNII:S270N0TRQY)	HYALURONIC ACID	0.3 mg in 15 g

Inactiva	Ingredients
HIACLIVE	mureulents

Ingredient Name	Strength

WATER (UNII: 059QF0KO0R)
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ 8H6N6OH)
DICHLOROBENZYL ALCOHOL (UNII: 1NKX3648J9)
SODIUM BENZOATE (UNII: OJ245FE5EU)

F	Packaging					
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:82160-566- 01	1 in 1 CARTON	01/15/2020			
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	
unapproved drug other		01/15/2020		

Labeler - Pella Pharmaceuticals Co. Ltd (562370925)

Revised: 12/2021 Pella Pharmaceuticals Co. Ltd