CICLOFERON- benzalkonium chloride and lidocaine hydrochloride gel
Laboratorios Liomont, S.A. de C.V.

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.

Drug Facts

Active Ingredients

Benzalkonium Chloride 0.13%

Lidocaine Hydrchloride 2%

Purpose

Topical antiseptic

Topical analgesic

Uses

- provides temporary relief of pain associated with cold sores and fever blisters
  - first aid to help protect against infection in minor cuts, scrapes, burns

Warnings

For external use only:

Do not use in the eyes or apply over large areas of the body. In case of deep puncture wounds, animal bites, or serious burns, consult a doctor.

Do not use

- for more than 7 days unless told to do so by a doctor
- more than directed
- if you are allergic to any ingredient in this product

When using this product

- avoid contact with the eyes

Stop use and ask a doctor if

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- clean the affected area
- apply a small amount of this product to the affected area 1 to 3 times daily
- may be covered with a sterile bandage
- children under 12 years of age, consult a doctor

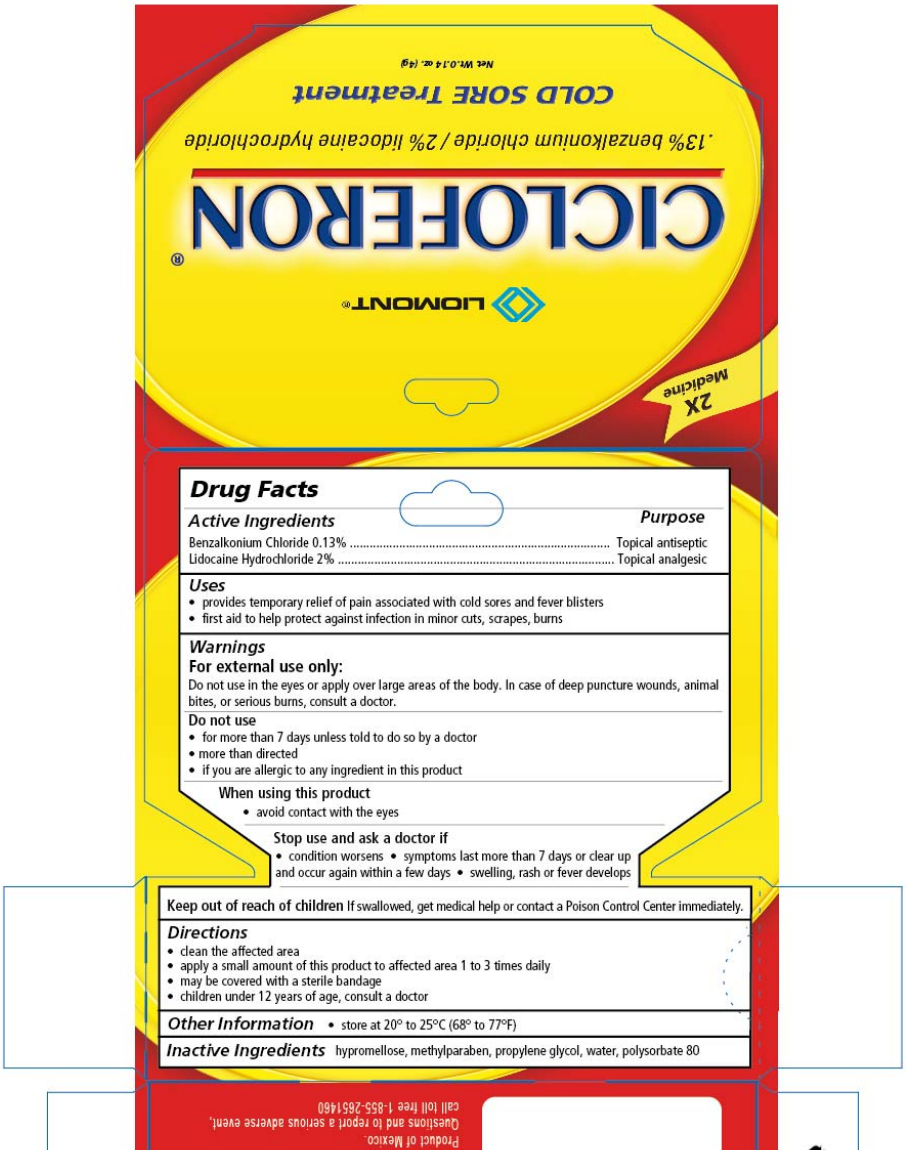
Other Information

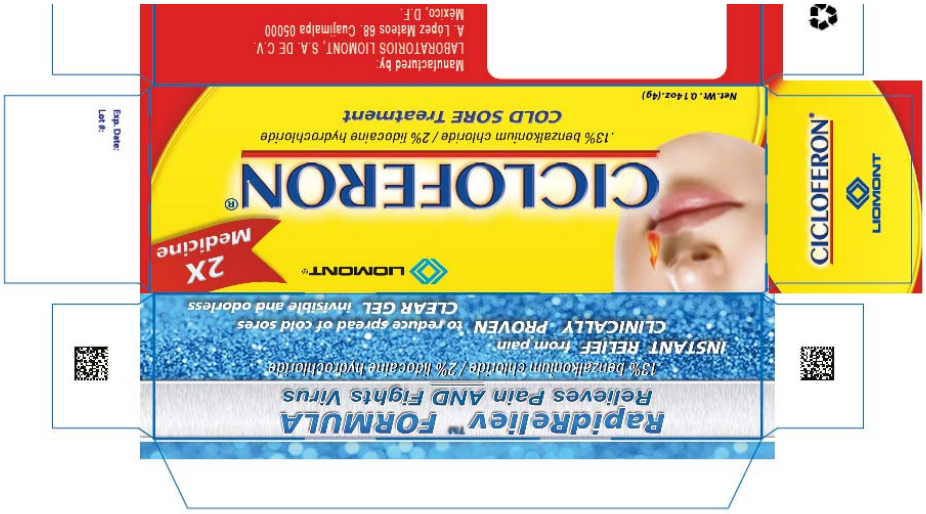
- store at 20° to 25°C (68° to 77°F)

Inactive Ingredients

hypromellose, methylparaben, propylene glycol, water, polysorbate 80

Package Label





CICLOFERON

benzalkonium chloride and lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59208-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 g
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59208-002-04	1 in 1 CARTON	05/01/2019	
1		4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:59208-002-05	1 in 1 CONTAINER	05/01/2019	

2	4 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 not final	part348	05/01/2019	

Labeler - Laboratorios Liomont, S.A. de C.V. (810347807)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Liomont, S.A. de C.V.		810347807	manufacture(59208-002)

Revised: 5/2019 Laboratorios Liomont, S.A. de C.V.