

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

CiclofrnGel

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 Drug | M003 | 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: 10/2024

Laboratorios Liomont, S.A. de C.V.