

**ZICLOVIN ORAL PAIN RELIEF- benzalkonium chloride, benzocaine gel
Pharmadel LLC**

Ziclovin Oral Pain Relief Gel (K)

Drug Facts

Active ingredients & Purposes

Active ingredients	Purposes
Benzalkonium chloride 0.1%.....	Topical antiseptic
Benzocaine 20%.....	Fever blister and cold sore treatment

Uses

For the temporary relief of pain due to

- fever blisters
- cold sores
- antiseptic to help prevent infection

Warnings

For external use only. Avoid contact with the eyes.

Methemoglobinemia warning: Use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops:

- pale, gray, or blue colored skin (cyanosis)
- headache
- rapid heart rate
- shortness of breath
- dizziness or lightheadedness
- fatigue or lack of energy

Allergy alert: do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use

- longer than 1 week
- on large areas of the body
- in the eyes

Ask a doctor before use

- in case of deep or puncture wounds, animal bites, or serious burns

When using this product

- you may feel a brief stinging sensation after application that will go away shortly thereafter

Stop use and ask a dentist or doctor if

- a rash or irritation develops
- condition persists or worsens
- symptoms persist for more than 7 days or clear up and occur again within a few days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

- **adults and children 2 years of age and older:** Clean the affected area. Apply a small amount to affected not more than 3 times daily. May be covered with a sterile bandage. If bandaged, let first dry.
- **children under 2 years of age:** do not use, consult a doctor

Other information

- store between 68-77°F (20-25°C)

Inactive ingredients

ammonium glycyrrhizate, carboxymethylcellulose sodium, FD&C yellow #6, glycerin, polyethylene glycol, saccharin sodium, sorbic acid, water

Questions?

Dist. by/por: **PHARMADEL LLC**

New Castle, DE 19720

Questions? +1-866-359-3478

NDC 55758-438-01

Ziclovin™

**Gel para el alivio instantáneo
del dolor oral**

**Tratamiento para
ampollas febriles
y herpes labial**

1oz (28g)



Ziclovin™

Instant Oral Pain Relief Gel

Fever blister and cold
sore treatment

Tratamiento para las ampollas
febriles y el herpes labial

Ziclovin™

**Instant Oral Pain
Relief Gel**

**Fever blister
and cold sore
treatment**

ZICLOVIN ORAL PAIN RELIEF

benzalkonium chloride, benzocaine gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-438
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	20 g in 100 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SORBIC ACID (UNII: X045WJ989B)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-438-01	1 in 1 CARTON	11/12/2024	
1		28 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	M017	11/12/2024	

Labeler - Pharmadel LLC (030129680)