ZYCAZIN ANTISEPTIC LIQUID- camphor, phenol liquid Axis Scientific LLC

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.

ZYCAZIN Antiseptic Liquid

Active ingredient

Camphorated phenol (camphor 10.8% and phenol 4.7%)

Purposes

Pain reliever/antiseptic

Uses

• for temporary relief of pain associated with

insect bites, minor burns, sunburn, minior cuts, scrapes, minor skin irritation, cold sores

• first aid to help protect against infection in

minor cuts, scrapes, minor burns

Warnings

For external use only

Do not use

- over large areas of the body
- with a bandage

Ask a doctor before use if you have

- a deep or puncture wound
- animal bites
- serious burns

When using this product

do not use in or near the eyes. If contact occurs, rinse eyes thoroughly with water and obtain medical attention.

Stop use and ask a doctor if

- condition worsens
- symptoms persis for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

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

Do not induce vomiting before contacting medical help or a Poison Control Center.

Directions

- adults and children 2 years and over:
- clean the affected area
- apply a small amount of this product on the area 1 to 3 times daily
- do not bandage
- children under 2 years: ask a doctor

Other information

- store at room temperature. Avoid excessive heat above 40°C (104°F).
- close cap tightly after use

Inactive ingredients

eucalyptus oil, light mineral oil

Questions or comments?

1-888-742-9474 (Mon - Fri 9AM - 5PM EST) or www.zycazin.com

Carton

Carton front





ZYCAZIN ANTISEPTIC LIQUID

camphor, phenol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70351-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CAMPHOR (NATURAL) (UNII: N20 HL7Q941) (CAMPHOR (NATURAL) - UNII:N20 HL7Q941)	CAMPHOR (NATURAL)	10.8 mg in 100 mL	
PHENOL (UNII: 339 NCG44TV) (PHENOL - UNII:339 NCG44TV)	PHENOL	4.7 mg in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
LIGHT MINERAL OIL (UNII: N6K5787QVP)		
EUCALYPTUS OIL (UNII: 2R040NI662)		
EUCALYPTUS OIL (UNII: 2R04ONI662)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70351-101-12	1 in 1 CARTON	11/0 1/20 16	
1		12 mL in 1 BOTTLE; 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	11/0 1/20 16		

Labeler - Axis Scientific LLC (057647986)

Establishment			
Name	Address	ID/FEI	Business Operations
Axis Scientific LLC		057647986	pack(70351-101), manufacture(70351-101), label(70351-101)

Revised: 10/2016 Axis Scientific LLC