ZURFLEX- pain relief spray spray Basler Health Care Group

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.

Active Ingredient

Menthol 9%

Purpose

Topical Analgesic

Uses

Temporarily relieves minor pain associated with

- simple backache
- arthritis
- tendonitis
- strains
- sprains
- pulled ligaments
- sore/stiff muscles
- sports injuries

Warnings

For external use only

When using this product

- use only as directed
- avoid contact with eyes
- do not apply to open wounds or damaged skin
- do not bandage tightly or use a heat pad

Stop use and ask a doctor if

- condition worsens or if symptoms persist for more than 7 days
- irritation develops
- redness is present

If pregnant or breast-feeding

ask a health professional; before use

Keep out of the reach of children

If accidentally ingested, seek medical help or contact a Poison Control Center immediately, Replace cap firmly.

Directions

• repeat as necessary but no more than 4 times daily

Children 2 years or younger ask a doctor

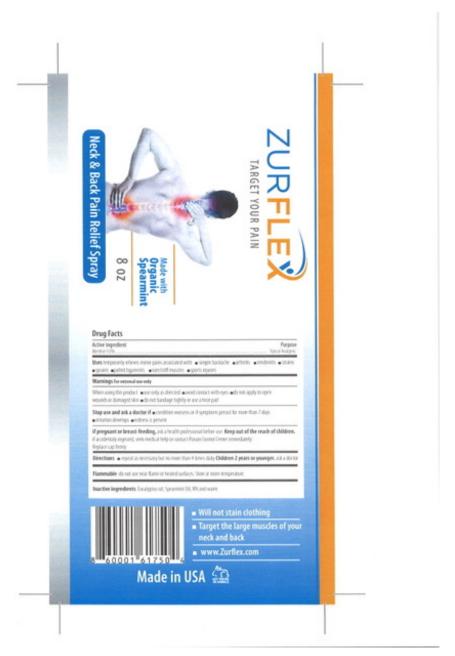
Flammable

Do not use near flame or heated surface. Store at room temperature.

Inactive Ingredients

Eucalyptus Oil, isopropyl alcohol, Spearmint Oil, Water

Bottle Label



ZURFLEX

pain relief spray spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72668-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	90 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
WATER (UNII: 059QF0KO0R)			
SPEARMINT OIL (UNII: C3M8 146 5G5)			
EUCALYPTUS OIL (UNII: 2R04ONI662)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:72668-00	- 237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/01/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	07/01/2020		

Labeler - Basler Health Care Group (794923128)

Establishment				
Name	Address	ID/FEI	Business Operations	
TAKA USA Inc. dba Cosmetic Inoovations		802860515	manufacture(72668-001)	

Revised: 11/2020 Basler Health Care Group