FIRST SHIELD- benzalkonium chloride, lidocaine hci cream
Unishield

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.

Unishield First Aid & Burn Cream

Active ingredient

Benzalkonium Chloride 0.13%

Lidocaine HCl 0.5%

Purpose

First aid antiseptic

Topical analgesic

Uses

- temporary relief of pain associated with minor burns
- helps protect against harmful bacteria

Warnings

For external use only.

Do not use

- in eyes
- in large quantities
- over raw surfaces or blistered areas, or on deep puncture wounds, animal bites, serious burns
- for more than one week unless directed by a doctor

Keep out of reach of children.

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

Directions

- clean affected area
- apply a small amount not more than 3-4 times daily
- children under 2 years: do not use,consult a doctor

Other Information

- store at room temperature (do not freeze)
- tamper evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

aloe barbadensis leaf juice, cetearyl alcohol, disodium EDTA,ethylhexylglycerin, glycerin, glyceryl stearate, mineral oil, maltodextrin, propylene glycol,purified water, PEG-100 Stearate, phenoxyethanol, stearic acid, triethanolamine

Questions or comments?

1-800-480-5855

First Aid & Burn Cream

First Aid Antiseptic & Topical Anesthetic

Dist by: UniShield

Net Wt. 0.9 g(1/32 oz)

Made in China

Drug Facts

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Benzalkonium Chloride 0.13%	First aid antiseptic
Lidocaine HCl 0.5%	Topical analgesic

Uses ■ temporary relief of pain associated with minor burns ■ helps protect against harmful bacteria

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Keep out of reach of children. If ingested, get medical help or contact a Poison Control Center right away

Directions ■ clean affected area ■ apply a small amount not more than 3-4 times daily ■ **Children under 2 years:** do not use, consult a doctor

Inactive ingredients aloe barbadensis leaf juice, cetearyl alcohol, disodium EDTA, ethylhexylglycerin, glycerin, glyceryl stearate, mineral oil, maltodextrin, propylene glycol, purified water, PEG-100 Stearate, phenoxyethanol, stearic acid, triethanolamine

FIRST SHIELD

benzalkonium chloride, lidocaine hci cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:49314-0003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5 mg in 1 g
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MINERAL OIL (UNII: T5L8T28FGP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
PEG-100 STEARATE (UNII: YD01N1999R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49314-0003-2	25 in 1 BOX	04/03/2023	
1	NDC:49314-0003-1	0.9 g in 1 POUCH; 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	04/03/2023	

Labeler - Unishield (790677053)

Revised: 4/2023 Unishield