FREDS ANTISEPTIC WASH - benzalkonium chloride and lidocaine hydrochloride liquid Pharma Pac, 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.

drug facts

Active ingredient Purpose

Benzalkonium chloride 0.13%......First Aid Antiseptic Lidocaine hydrochloride 2%......External Antiseptic

Uses- to help reduce the risk of infection in minor cuts scrapes and burns

- for the temporary relief of pain and itching associated with minor cuts, scrapes and burns

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately

Uses

- to help reduce the risk of infection in minor cuts scrapes and burns
- for the temporary relief of pain and itching associated with minor cuts, scrapes and burns

Directions

- adults and children 2 years and older:
- use to clean minor cut, scrapes and burns by thoroughly flushing the affected area
- let air dry
- cover with adhesive bandage or sterile gauze
- apply a small amount of this product on the area 1 to 3 times daily
- children under 2 years: Do not use, consult a doctor

Warnings For external use only.

Do not use

- in large quantities, particularly over raw surfaces or blistered areas

Ask a doctor before use if you have - deep or puncture wounds

- animal bites - serious burns

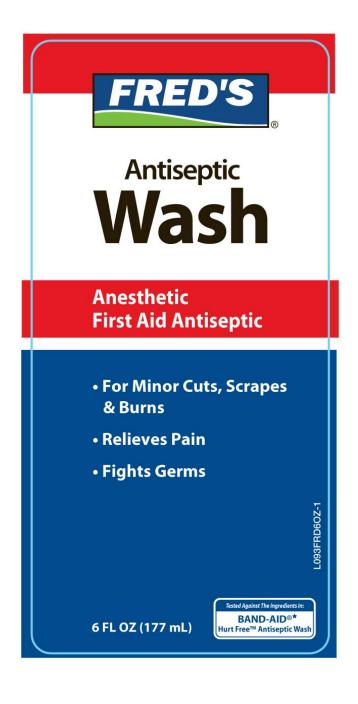
Stop use and ask a doctor if - condition worsens - symptoms persist for more than 7 days, or clear up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- adults and children 2 years and older:
- use to clean minor cut, scrapes and burns by thoroughly flushing the affected area
- let air dry
- cover with adhesive bandage or sterile gauze
- apply a small amount of this product on the area 1 to 3 times daily
- children under 2 years: Do not use, consult a doctor

Inactive Ingredients aloe barbadensis gel, poloxamer 188, sodium chloride, sodium citrate, disodium EDTA, water



Drug Facts Active ingredients **Purpose** Benzalkonium chloride 0.13% First Aid Antiseptic Lidocaine hydrochloride 2% External Antiseptic **Uses** to help reduce the risk of infection in minor cuts, scrapes and burns for the temporary relief of pain and itching in minor cuts, scrapes and burns **Warnings** For external use only Do not use ■ in large quantities, particularly over raw surfaces or blistered areas Ask a doctor before use if you have ■ deep or puncture wounds ■ animal bites ■ serious burns Stop use and ask a doctor if ■ condition worsens symptoms persist 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 immediately adults and children 2 years of age and older: ■ use to clean minor cut, scrapes and burns by thoroughly flushing the affected area ■ let air dry ■ cover with adhesive bandage or sterile gauze apply a small amount of this product on the area 1 to 3 times daily children under 2 years of age: Do not use, consult a doctor **Inactive ingredients** aloe barbadensis gel, poloxamer 188, sodium chloride, sodium citrate, disodium EDTA, water ★ This product is not **FRED'S Promise** manufactured or distributed Not Happy With This Product? Just Bring It Back For a Refund! by Johnson and Johnson® owner of the trademarks Band-Aid® Hurt Free™

FREDS ANTISEPTIC WASH

benzalkonium chloride and lidocaine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67868-054
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 mL	
LIDO CAINE HYDRO CHLO RIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	20 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
POLOXAMER 188 (UNII: LQA7B6G8JG)			
EDETATE DISO DIUM (UNII: 7FLD91C86K)			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
ANHYDRO US TRISO DIUM CITRATE (UNII: RS7A450 LGA)			

Packaging				
1	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:67868-054-39	177 mL in 1 BOTTLE, DISPENSING		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part333A	07/08/2010			

Labeler - Pharma Pac, LLC (140807475)

Registrant - Pharma Pac, LLC (140807475)

Establishment				
Name	Address	ID/FEI	Business Operations	
Pharma Pac, LLC		140807475	manufacture	

Revised: 7/2010 Pharma Pac, LLC