WESTERN FAMILY ALOE VERA MOISTURIZING - lidocaine hydrochloride gel
WESTERN FAMILY FOODS, INC.

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

Lidocaine HCl 0.5%

Purpose

Topical Analgesic

Uses

- temporary relief of pain and itching
- helps relieve and soothes pain from sunburn, minor burns, cuts, scrapes, skin irritations and insect bites

Warnings

For external use only

Do not use

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

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- condition worsens or if symptoms persist for more than 7 days.
- symptoms 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

Directions

- adults and children 2 years of age and older: apply to affected areas not more than 3 to 4 times daily
- children under 2 years of age: do not use, ask a doctor

Inactive ingredients

Water, Propylene Glycol, Glycerin, Isopropyl Alcohol, Triethanolamine, Polysorbate 80, Carbomer, Aloe Barbadensis Leaf Juice Powder, Menthol, Disodium EDTA, Diazolidinyl Urea, Yellow 5, Blue 1.

Principal Display Panel

WESTERN FAMILY

Aloe Vera

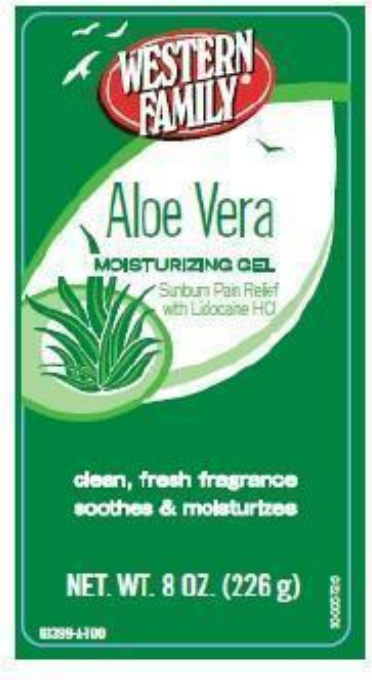
MOISTURIZING GEL

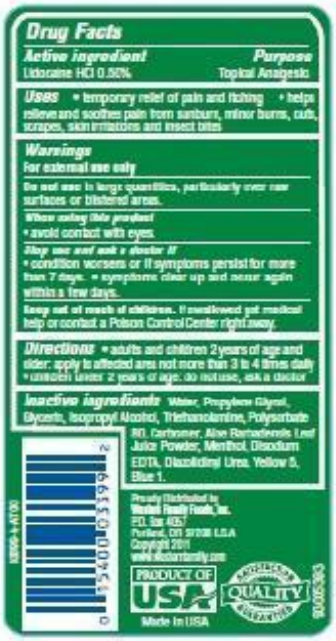
Sunburn Pain Relief

with Lidocaine HCL

clean, fresh fragrance soothes and moisturizes

NET WT. 8 OZ. (226 g)





WESTERN FAMILY ALOE VERA MOISTURIZING

lidocaine hydrochloride gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55312-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	0.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
TROLAMINE (UNII: 9O3K93S3TK)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MENTHOL (UNII: L7T10EIP3A)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:55312-012-16	226 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/02/2014	

Labeler - WESTERN FAMILY FOODS, INC. (192166072)

Revised: 7/2014 WESTERN FAMILY FOODS, INC.