ASSURED BUG BITE RELIEF- sodium bicarbonate liquid Shanghai Weierya Daily Chemicals Factory

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

Sodium Bicarbonate (Baking Soda) 5%

Purpose

Skin Protectant

Uses temporary relief of itching and irritation due to

-insect bites and stings -poison ivy, oak or sumac

Warnings

For external use only

Do not use

- over large areas of the body
- other than as directed

When using this product

• avoid contact with eyes

Stop use and ask a doctor if

- symptoms last for more than 7 days
- the condition becomes worse
- symptoms clear up and then 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 over 2 years of age:

-apply a small amount of directly to the bite, sting or affected

area and rub gently

-re-apply as needed

children under 2 years of age: ask a doctor before use

Other information

store at room temperature 59 - 86 F (15 - 30 C)

Inactive ingredients ammonia, cyclohexasiloxane,

cyclopentasiloxane, glycerin, water

Assured's Bug Bite Relief helps to relieve a wide range

of irritation and itching associated with the most common

and annoying insect bites. When you feel the sting, reach

for the soothing relief of Assured's Bug Bite Relief.

Easy. Convenient. Effective.

Always keep it with you. On - the - go or at home.



0.5 FL. OZ. (14 mL
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ASSURED BUG BITE R	ELIEF						
sodium bicarbonate liquid							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source)		NDC:58194-039			
Route of Administration	TOPICAL						
Active Ingredient/Active Moiety							
Ingredient Name Basis of S				Strength	Strength		
SODIUM BICARBONATE (UNII: 8 MDF	5V39QO) (SODIUM CATION - U	JNII:LYR4M0NH37)	SODIUM BIC	ARBONATE	5 g in 100 g		
Inactive Ingredients							
Ingredient Name			Strength				
AMMO NIA (UNII: 5138Q19F1X)							
GLYCERIN (UNII: PDC6A3C0OX)							
CYCLOMETHICONE 6 (UNII: XHK3U3	10 BA)						
CYCLOMETHICONE 5 (UNII: 0 THT5PC	C10 R)						

WATER (UNII: 059QF)KO0R)						
Packaging							
# Item Code	Package Description	Marketing Start Date	Marketing End Date				
1 NDC:58194-039-01	14 g in 1 APPLICATOR; Type 0: Not a Combination Produc	t 11/10/2015					
Marketing Information							
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph final	part347	11/10/2015					

Labeler - Shanghai Weierya Daily Chemicals Factory (420359333)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Weierya Daily Chemicals Factory		420359333	manufacture(58194-039)

Revised: 6/2016

Shanghai Weierya Daily Chemicals Factory