BACTINE MAX DRY- lidocaine hydrochloride spray WellSpring Pharmaceutical Corporation

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.

Bactine[®] Max Pain Relieving Cleansing Spray

Drug Facts

Active Ingredients

Lidocaine 4%

Purpose

Pain Relieving Spray

Uses

For the temporary relief of pain and itching associated with minor burns, sunburn, minor cuts, scrapes, insect bites or minor skin irritations.

Warnings

For external use only

Do not Use

- in large quantities, particularly over raw surfaces or blister areas
- on puncture wounds
- in or near the eyes
- longer than 1 week unless directed by a doctor

When using this product

- use only as directed. Read and follow all directions and warnings on this label.
- \blacksquare do not allow contact with the eyes and mucous membranes
- avoid spraying on face
- avoid inhalation of spray
- do not bandage or apply local heat (such as heating pads) or a medicated patch to

area of use

■ do not use at the same time as other topical analgesics

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

Extremely Flammable

- do not use near heat or flame or while smoking
- avoid long term storage above 104°F (40°C)
- do not puncture or incinerate. Contents under pressure.
- do not store at temperatures above 120°F (49°C)

If pregnant or breast-feeding

ask a health professional before use.

Keep out of reach of children.

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

Directions

■ adults and children over 12 years:

■ spray affected area every 6 to 8 hours, not to exceed 3 to 4 applications in a 24 hour period

- product will dry quickly on its own, and does not need to be rubbed in
- children 12 years or younger: ask a doctor

Child-resistant packaging. Replace cap after each use

Inactive ingredients

alcohol denat. (28 %) anthemis nobilis flower oil aqua arnica montana flower extract calendula officinalis flower extract Caprylic/Capric Triglyceride glycerin isobutane propylene glycol

Questions?

1-844-241-5454 or www.bactine.com

Distributed by:

WellSpring Pharmaceutical Corporation Sarasota, FL 34243 © 2022 Wellspring Pharmaceutical Corporation MONEYBACK GUARANTEE Bactine max is FSA/HSA eligible DOT 2Q M5706 Extremely Flammable

PRINCIPAL DISPLAY PANEL

NEW NDC 65197-815-04 Bactine MAX LIDOCAINE Dry Spray Anesthetic NUMBS AWAY PAIN AND ITCH MAX RELIEF FOR Minor Cuts & Scrapes, Burns, Bug bites & Sunburn QUICK-DRY 4oz (175mL)

Drug Facts (continued)		Drug Facts
If pregnant or breast-feeding ask a health professional before use.	NEW () Dation	Active ingredients Purpose Lidocaine 4% Pain Relieving Spray
Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.	Dallie	Uses For the temporary relief of pain and itching associated with minor burns, sunburn,
Directions adults and children over 12 years: spray	MAX	minor cuts, scrapes, insect bites or minor skin irritations.
affected area every 6 to 8 hours, not to exceed 3 to 4 applications in a 24 hour period product will dry quickly on its own,		Warnings For external use only.
and does not need to be rubbed in children 12 years or younger: ask a doctor	LIDOCAINE	Do not Use in large quantities, particularly over raw surfaces or blister areas on puncture wounds
Inactive Ingredients alcohol denat. (28%), anthemis nobilis	DRY SPRAY	■ in or near the eyes ■ longer than 1 week unless directed by a doctor
flower oil, aqua, arnica montana flower extract, calendula officinalis flower extract, Caprylic/Capric Triglyceride, glycerin, isobutane, propylene glycol	ANESTHETIC	When using this product use only as directed. Read and follow all directions and warnings on this label do not allow contact with the eyes and mucous
Questions? 1-844-241-5454 or www.Bactine.com	C	membranes ■ avoid spraying on face ■ avoid inhalation of spray ■ do not bandage or apply local heat (such as
hild-resistant packaging. Replace cap after each use. istributed by: WellSpring	NUMBS AWAY PAIN AND ITCH	heating pads) or a medicated patch to area of use a do not use at the same time as other topical analgesics
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Extremely Flammable	QUICK-DRY 4 oz (175mL)	under pressure ■ do not store at temperatures above 120°F (49°C)
	Bactine Dry Spray 4oz	

idocaine hydrochloride spra	У				
Product Information					
Product Type	HUMAN OTC DRUG	ltem (Code (Source)	NDC:651	97-815
Route of Administration	TOPICAL				
Active Ingredient/Active	e Moiety				
Ingredi	ent Name		Basis of Streng	jth	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)		≣ -	LIDOCAINE HYDROCHLORIDE ANHYDROUS		5 g in 100 mL
Inactive Ingredients					
	Ingredient Name			St	trength
CHAMAEMELUM NOBILE FLOW	/ER OIL (UNII: UB27587839)				
ARNICA MONTANA FLOWER (U	NII: OZ0E5Y15PZ)				
CALENDULA OFFICINALIS FLO	WER (UNII: P0M7O4Y7YD)				
WATER (UNII: 059QF0KO0R)					
MEDIUM-CHAIN TRIGLYCERIDE	S (UNII: C9H2L21V7U)				
GLYCERIN (UNII: PDC6A3C0OX)					

AL	ALCOHOL (UNII: 3K9958V90M)									
Product Characteristics										
Color		white	Score							
Sł	Shape			Size						
Fla	avor			Imprint Code						
Сс	ontains									
Pa	ackaging									
		Package Description			Markating Start	Maylesting Fiel				
#	Item Code	Pacl	cage Descriptio	on	Marketing Start Date	Marketing End Date				
	NDC:65197-815-		Kage Descriptic N; Type 0: Not a Col							
	NDC:65197-815-	175 mL in 1 CA			Date					
	NDC:65197-815-	175 mL in 1 CA			Date					
1	NDC:65197-815-	175 mL in 1 CAI Product	N; Type 0: Not a Co		Date					
1	NDC:65197-815- 04	175 mL in 1 CAP Product nformati	N; Type 0: Not a Co	mbination	Date					
1	NDC:65197-815- 04 Iarketing I Marketing Category TC monograph not	175 mL in 1 CAP Product nformatic Applicati	N; Type 0: Not a Con ON ON Number or M	mbination	Date 01/31/2023 Marketing Start	Date Marketing End				

Labeler - WellSpring Pharmaceutical Corporation (110999054)

Revised: 12/2022

WellSpring Pharmaceutical Corporation