

ASPIERA WOUND CARE AND ANTISEPTIC - allantoin, benzethonium chloride ointment
Aidance Skincare & Topical Solutions, 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

Allantoin 0.5%

Benzethonium Chloride 0.1%

Purpose

Allantoin - Skin Protectant

Benzethonium Chloride - First Aid Antiseptic

Uses

- Helps protect skin and supports healing of minor cuts, scrapes, burns and wounds, including pressure sores, diabetic ulcers, cracked skin and lips.
- Topical antiseptic to help decrease the risk of skin infection.

Warnings

For external use only.

When using this product, do not get into eyes.

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

Do not use on deep or puncture wounds, animal bites or serious burns.

Keep out of reach of children.

If swallowed, call poison control or seek medical help.

Directions

Wash and dry affected skin. Apply a thin layer of Aspiera. Cover affected area with a clean bandage. Repeat procedure 1-3 times daily until skin improves. Store at room temperature.

Inactive Ingredients


bentonite, cera alba (organic beeswax), magnesium oxide, peppermint oil, sage oil, silver oxide, simmondsia chinensis (jojoba) seed oil, zinc oxide

Made in USA. Distributed by Aspiera Medical, a division of Aidance Skincare & Topical Solutions, LLC. (+1) 401-400-0047 www.aspiera.com

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PRINCIPAL DISPLAY PANEL - 44g Label

Aspiera Wound Care and Antiseptic Ointment Faster Penetration for Faster Healing™

Drug Facts	Faster Penetration for Faster Healing™	Directions: Wash and dry affected skin. Apply a thin layer of Aspiera ointment. Cover affected area with a clean bandage. Repeat procedure 1-3 times daily until skin improves. Store at room temperature.	Aspiera Medical Division
Active Ingredients Purpose Allantoin 0.5% Skin Protectant Benzethonium Chloride 0.1% First Aid Antiseptic	 <p>Aspiera™ Wound Care and Antiseptic Ointment</p> <p>NET WT 44 grams</p>	Inactive Ingredients: bentonite clay, cera alba (organic beeswax), magnesium oxide, peppermint oil, sage oil, silver oxide, simmondsia chinensis (jojoba) seed oil, zinc oxide	
Uses: • Helps protect skin and supports healing of minor lacerations, scrapes, burns and wounds, including pressure sores, diabetic ulcers, and cracked skin. • Topical antiseptic to help decrease the risk of skin infection.		<small>Made in USA. Distributed by Aspiera Medical, a division of Aidance Skincare & Topical Solutions, LLC. (1) 801-488-0847 www.aspiera.com Protected by US and international patents granted and pending. Aspiera™ and Faster Penetration for Faster Healing™ are trademarks of Aidance Skincare. © 2012 Aidance Skincare</small>	
Warnings: For external use only. When using this product, do not get into eyes. Stop use and ask a doctor if condition worsens, symptoms last more than 7 days or clear up and occur again within a few days. Do not use on deep or puncture wounds, animal bites or serious burns. Keep out of reach of children. If swallowed, call poison control or seek medical help.			

ASPIERA WOUND CARE AND ANTISEPTIC

allantoin, benzethonium chloride ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:249 09-617
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.5 g in 100 g
BENZETHONIUM CHLORIDE (UNII: PH41D05744) (BENZETHONIUM - UNII:1VU15B70BP)	BENZETHONIUM CHLORIDE	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENTONITE (UNII: A3N5ZCN45C)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SAGE OIL (UNII: U27K0H1H2O)	
SILVER OXIDE (UNII: 897WUN6G6T)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:24909-617-44	44 g in 1 JAR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part347	05/31/2012	

Labeler - Aidance Skincare & Topical Solutions, LLC (018950611)

Establishment

Name	Address	ID/FEI	Business Operations
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture, label

Revised: 5/2012

Aidance Skincare & Topical Solutions, LLC