FASTRIN INCONTINENCE AND OSTOMY RASH CARE- calendula, comfrey, thuja occidentalis ointment

Aidance Skincare & Topical Solutions, LLC

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Drug Facts

Active Ingredient

Calendula officinalis 1X HPUS, Comfrey (Symphytum officinale) 1X HPUS, Thuja occidentalis 3X HPUS

Purpose

Calendula - Healing Agent, Comfrey - Anti-Inflammatory, Thuja - Irritation Relief

Uses

Helps relieve and prevent rashes and irritation due to wetness from incontinence. Helps prevent infection.

Warnings

For external use only. Do not get into eyes.

Keep out of reach of children.

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

Directions

Clean and dry affected skin. Apply a thin layer of ointment over the affected area. Repeat 1 to 3 times daily or as needed.

Inactive Ingredients

Beeswax, Cottonseed Oil, Jojoba Seed Oil, Magnesium Oxide, Manuka Honey, Peppermint Oil, Silver Oxide, Tea Tree Oil, Zinc Oxide

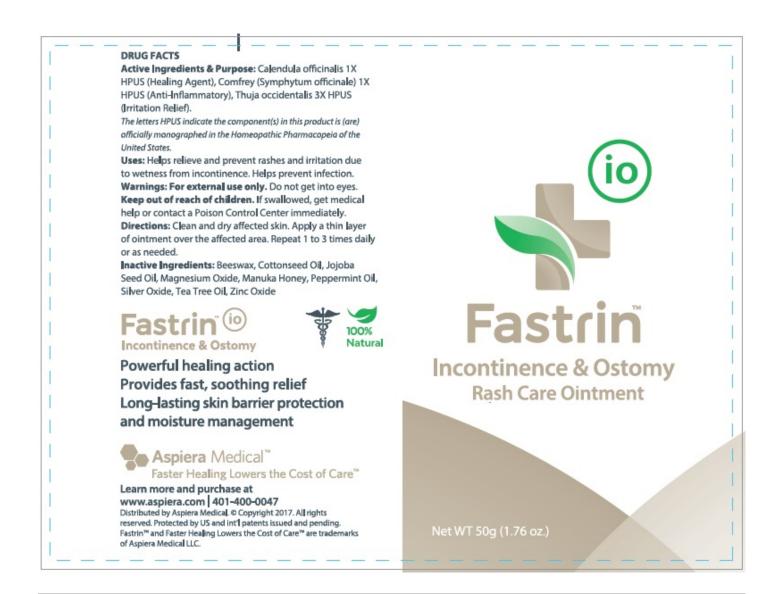
PRINCIPAL DISPLAY PANEL - 50g Tube

Fastrin

Incontinence & Ostomy

Rash Care Ointment

Net WT 50g (1.76 oz.)



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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:24909-603	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) (CALENDULA OFFICINALIS FLOWER - UNII:P0M7O4Y7YD)	CALENDULA OFFICINALIS FLOWER	1 [hp_X] in 100 g	
COMFREY (UNII: D05HXK6R3G) (COMFREY - UNII:D05HXK6R3G)	COMFREY	1 [hp_X] in 100 g	
THUJA O CCIDENTALIS WHO LE (UNII: 5HBV6WCE3N) (THUJA OCCIDENTALIS WHO LE - UNII:5HBV6WCE3N)	THUJA OCCIDENTALIS WHOLE	3 [hp_X] in 100 g	

Inactive Ingredients	
Ingredient Name	Strength

COTTONSEED OIL (UNII: H3E878020N)	
HO NEY (UNII: Y9 H1V576 FH)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM O XIDE (UNII: 3A3U0 GI71G)	
PEPPERMINT OIL (UNII: AV092KU4JH)	
SILVER OXIDE (UNII: 897WUN6G6T)	
TEA TREE OIL (UNII: VIF565UC2G)	
WHITE WAX (UNII: 7G1J5DA97F)	
ZINC OXIDE (UNII: SOI2LOH54Z)	

]	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:24909-603-10	10 g in 1 JAR; Type 0: Not a Combination Product	06/01/2017		
2	NDC:24909-603-50	50 g in 1 TUBE; Type 0: Not a Combination Product	06/01/2017		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		06/01/2017		

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Aidance Skincare & Topical Solutions, LLC		018950611	manufacture(24909-603), label(24909-603)	

Revised: 6/2017 Aidance Skincare & Topical Solutions, LLC