

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.)

DRUG FACTS

Active Ingredients & Purpose: Calendula officinalis 1X HPUS (Healing Agent), Comfrey (Symphytum officinale) 1X HPUS (Anti-Inflammatory), Thuja occidentalis 3X HPUS (Irritation Relief).

The letters HPUS indicate the component(s) in this product is (are) officially monographed in the Homeopathic Pharmacopeia of the United States.

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Fastrin ^{io}
Incontinence & Ostomy



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calendula, comfrey, thuja occidentalis ointment

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 OCCIDENTALIS WHOLE (UNII: 5HBV6WCE3N) (THUJA OCCIDENTALIS WHOLE - UNII:5HBV6WCE3N)	THUJA OCCIDENTALIS WHOLE	3 [hp_X] in 100 g

Inactive Ingredients

Ingredient Name	Strength
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COTTONSEED OIL (UNII: H3E878020N)	
HONEY (UNII: Y9H1V576FH)	
JOJOBA OIL (UNII: 724GKU717M)	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G)	
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