

HYDROSEPTINE- zinc oxide, menthol ointment
AKRON PHARMA INC

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.

MEDPURA
Hydroseptine Ointment
Protects, Soothes, Helps Promote Healing

Active Ingredients

Menthol 0.44%

Zinc Oxide 20.6%

Purpose

Active Ingredients	Purpose
Menthol 0.44%.....	External analgesic/anti-itch
Zinc Oxide 20.6%.....	Skin protectant/anorectal astringent

Uses

- A moisture barrier that prevents and heals skin irritations from
- urine
- diarrhea
- perspiration
- fistula drainage
- feeding tube site leakage
- wound drainage (peri-wound skin)
- minor burns
- cuts
- scrapes
- itching

Warnings

For external use only

When using this product

- not for deep or punctured wounds
- avoid contact with eyes

Stop use and ask doctor if

- In case of accidental ingestion contact a physician or Poison Control Center right away

- if condition worsens or does not improve within 7 days, consult a doctor

Keep out of reach of children.

Directions

Cleanse skin gently with mid skin cleanser. Pat dry or allow to air dry. apply a thin layer of Hydroseptine Ointment to reddened or irritated skin 2-4 times daily, or after each incontinent episode or diaper change to promote comfort and long lasting protection.

Inactive Ingredients:

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

Inactive ingredients calamine, chlorothymol, glycerin, lanoline, phenol, sodium bicarbonate, and thymol in a suitable ointment base

Questions or Comments? Call toll-free 1-877-255-6999



Manufactured for:

Akron Pharma, Inc.

Fairfield, NJ 07004

www.akronpharma.com

This product is not manufactured or distributed by Calmoseptine Inc., owner of the registered trademark Calmoseptine.

	<p>Drug Facts</p> <p>Active ingredients Menthol 0.44%.....External analgesic/anti-itch Zinc Oxide 20.6%.....Skin protectant/anorectal astringent</p> <p>Uses A moisture barrier that prevents and helps heal skin irritations from ■ urine ■ diarrhea ■ perspiration ■ fistula drainage ■ feeding tube site leakage ■ wound drainage (peri-wound skin) ■ minor burns ■ cuts ■ scrapes ■ itching</p> <p>Warnings For external use only ■ not for deep or puncture wounds ■ avoid contact with eyes ■ Keep out of reach of children ■ In case of accidental ingestion contact a physician or Poison Control Center right away ■ if condition worsens or does not improve within 7 days, consult a doctor.</p> <p>Directions ■ cleanse skin gently with mild skin cleanser. Pat dry or allow to air dry. Apply a thin layer of Hydroseptine Ointment to reddened or irritated skin 2-4 times daily, or after each incontinent episode or diaper change to promote comfort and long lasting protection.</p>	<p>Drug Facts (continued)</p> <p>Other information store at room temperature 15°-30°C(59°-86°F)</p> <p>Inactive ingredients calamine, chlorothymol, glycerin, lanolin, phenol, sodium bicarbonate, and thymol in a suitable ointment base</p> <p>Questions or comments? Call toll-free 1-877-255-6999.</p> <p>*This product is not manufactured or distributed by Calmoseptine Inc., owner of the registered trademark Calmoseptine.®</p> <p>Akron Pharma Manufactured for: Akron Pharma, Inc. Fairfield, NJ 07004 www.akronpharma.com</p>
	<p>NDC 71399-6743-1</p> <p>Hydroseptine™ Ointment</p> <p>Protects, Soothes, Helps Promote Healing</p> <p>● Zinc Oxide 20.6% ● Menthol 0.44%</p> <p>Compare to the active ingredients in Calmoseptine® Ointment*</p> <p>For External Use Only</p> <p>Made in USA  NET WT. 3.53 OZ (100g)</p>	

HYDROSEPTINE			
zinc oxide, menthol ointment			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71399-6743
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength

MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.44 g in 100 g
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20.6 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CHLOROTHYMOL (UNII: LJ25TI0CVT)	
GLYCERIN (UNII: PDC6A3C0OX)	
LANOLIN (UNII: 7EV65EAW6H)	
PHENOL (UNII: 339NCG44TV)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
THYMOL (UNII: 3J50XA376E)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-6743-1	100 g in 1 JAR; Type 0: Not a Combination Product	11/05/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part346	11/05/2021	

Labeler - AKRON PHARMA INC (067878881)

Revised: 3/2023

AKRON PHARMA INC