

MADECASSOL- neomycin sulfate, titrated ext. of centella asiatica ointment
I World Pharmaceutical Co., Ltd.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Neomycin Sulfate, Titrated Ext. of Centella Asiatica

■ temporary relief of itching associated with minor skin irritations and rashes due to eczema, insect bites, poison ivy, poison oak, or poison sumac soaps detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis, external genital and anal itching

Keep out of reach of children

■ Adults and children 2 years of age and older: apply to the affected area no more than 3 to 4 times daily

For external use only.

Do not use in the eyes by putting this product into the rectum by using fingers or any mechanical device or applicator.

Ask a doctor before use if you have a vaginal discharge, rectal bleeding, diaper rash.

When using this product consult a doctor before exceeding recommended dosage.

Stop use and ask a doctor if condition gets worse, condition persists for more than 7 days, condition clears up and occurs again within a few days. Do not begin to use any other hydrocortisone product unless you have consulted a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

cetostearyl alcohol, propylene glycol, purified water, sodium lauryl sulfate, white petrolatum

For external use only

MADECASSOL

<i>Drug Facts</i>	
<i>Active Ingredients (in 1g)</i>	<i>Purpose</i>
Neomycin Sulfate 3.5mg	Anti-itch
Titrated Ext. of Centella Asiatica 10mg	Anti-itch
<i>Uses</i>	
■ temporary relief of itching associated with minor skin irritations and rashes due to eczema, insect bites, poison ivy, poison oak, or poison sumac soaps detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis, external genital and anal itching	
<i>Warnings</i>	
For external use only. Do not use in the eyes by putting this product into the rectum by using fingers or any mechanical device or applicator. Ask a doctor before use if you have a vaginal discharge, rectal bleeding, diaper rash. When using this product consult a doctor before exceeding recommended dosage. Stop use and ask a doctor if condition gets worse, condition persists for more than 7 days, condition clears up and occurs again with within a few days. Do not begin to use any other hydrocortisone product unless you have consulted a doctor. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<i>Directions</i>	
■ Adults and children 2 years of age and older: apply to the affected area no more than 3 to 4 times daily	
<i>Other Information</i>	
■ Store at room temperature	
<i>Inactive Ingredient</i>	
cetostearyl alcohol, propylene glycol, purified water, sodium lauryl sulfate, white petrolatum	
<i>Questions or comments ?</i>	
Call weekdays from 9 a.m to 5 p.m EST at (201) 669-8405 Distributed By: P&K FRONTIER MARKETING CORP. 329 BROAD AVENUE # 2F, PALISADES PARK, NJ 07650, USA	
Made in South Korea	

MADECASSOL

neomycin sulfate, titrated ext. of centella asiatica ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73442-0004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CENTELLA ASIATICA (UNII: 7M867G6T1U) (CENTELLA ASIATICA - UNII:7M867G6T1U)	CENTELLA ASIATICA	10 mg in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:116QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73442-0004-1	10 g in 1 TUBE; Type 0: Not a Combination Product	10/08/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/08/2019	

Labeler - IWorld Pharmaceutical Co., Ltd. (688222857)**Registrant** - IWorld Pharmaceutical Co., Ltd. (688222857)**Establishment**

Name	Address	ID/FEI	Business Operations
I World Pharmaceutical Co., Ltd		688222857	manufacture(73442-0004)

Revised: 11/2019

I World Pharmaceutical Co., Ltd.