

**MADECASSOL- centella asiatica gel**  
**Lydia 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.*

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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

**Warnings**

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.

Lavender oil, anhydrous ethanol, sodium hydroxide, purified water, propylene glycol.

for topical use

## MADECASSOL Gel

<b>Drug Facts</b>	
<b>Active Ingredients (in 1g)</b>	<b>Purpose</b>
Titrated Ext. of Centella Asiatica 10mg	Anti-itch
<b>Uses</b>	
■ 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	
<b>Warnings</b>	
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. <b>Ask a doctor before use if you have</b> a vaginal discharge, rectal bleeding, diaper rash. <b>When using this product</b> consult a doctor before exceeding recommended dosage. <b>Stop use and ask a doctor if</b> 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. <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
■ Adults and children 2 years of age and older: apply to the affected area no more than 3 to 4 times daily	
<b>Other Information</b>	
■ Store at room temperature	
<b>Inactive Ingredient</b>	
Lavender oil, anhydrous ethanol, sodium hydroxide, purified water, propylene glycol.	
<b>Distributed By: Bio Mission Group, Inc.</b> 9925 Painter Ave #O, Whittier, CA 90605 USA	
<b>Made in South Korea</b>	

centella asiatica gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72988-0039
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>CENTELLA ASIATICA</b> (UNII: 7M867G6T1U) (CENTELLA ASIATICA - UNII:7M867G6T1U)	CENTELLA ASIATICA	10 mg in 1 g

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

### Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:72988-0039-1	10 g in 1 TUBE; Type 0: Not a Combination Product	09/01/2024	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
unapproved drug other		09/01/2024	

**Labeler** - Lydia Co., Ltd. (695735569)

**Registrant** - Lydia Co., Ltd. (695735569)

### Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Lydia Co., Ltd.		695735569	manufacture(72988-0039)

Revised: 9/2024

Lydia Co., Ltd.