

**DRUIDE BIOLOVE FOR DIAPER RASH- kaolin paste**  
**LABORATOIRES DRUIDE 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.*

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**DRUIDE BIOLOVE PASTE FOR DIAPER RASH 60 g**

***DRUG FACTS***

***Active Ingredients***

Kaolin 4.0%

***Purpose***

Skin Protectant

***Uses***

■ Helps prevent diaper rash ■ Protects chafed skin (or minor skin irritation) due to diaper rash ■ Helps protect from wetness that causes diaper rash ■ Temporarily helps relieve minor skin irritation due to diaper rash.

***Warnings***

**For external use only**

**Do not use**

on damaged or broken skin.

**When using this product**

keep out of eyes.

**Stop use and ask a doctor if**

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days.

**Keep out of reach of children**

If swallowed, get medical help or contact Poison Control Center right away.

## Directions

■ Change wet and soiled diapers promptly ■ Cleanse the diaper area ■ Allow to dry ■ apply ointment liberally as often as necessary, with each diaper change, especially at bedtime or any time when exposure to wet diapers may be prolonged.

## Other Information

Keep in a cool place to prevent the paste from melting.

## Inactive Ingredients

Carnauba Wax, Tocopherol, Acemella Oleracea, Olea Europaea (Olive) Oil\*, Chamomile Oil\*, Jojoba Esters, Calendula Officinalis Extract\*, Avena Sativa (Oat) Kernel Flour\*, Helianthus Annuus (Sunflower) Seed Oil\*, Candelilla Wax, Shea Butter\*.




\*Certified Organic.

## Questions or Comments?

1-800-263-8888

Outside Canada or the United States dial **514-333-8282** or visit [www.druidebio.com](http://www.druidebio.com)

## DRUIDE BIOLOVE PASTE FOR DIAPER RASH 60 G (NDC 71447-300-00)

	<b>DRUIDE BIOL<sup>o</sup>VE</b> No Zinc Paste for Diaper Rash 60g • 2.11 oz e		<b>DRUG FACTS</b>	<b>Purpose</b> Skin protectant
			<b>Active Ingredients</b> Kaolin 4%	<b>Uses:</b> • Helps prevent diaper rash • Protects chafed skin (or minor skin irritation) due to diaper rash • Helps protect from wetness that causes diaper rash • Temporarily helps relieve minor skin irritation due to diaper rash.
			<b>Warnings:</b> • For external use only • Avoid contact with eyes • Consult a healthcare practitioner if symptoms worsen or last for more than 7 days.	
			<b>Directions:</b> • Change wet and soiled diapers promptly • Cleanse the diaper area • Allow to dry • Apply paste liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged.	
			<b>Other Information:</b> Keep in a cool place to prevent the paste from melting.	
			<b>Inactive Ingredients:</b> HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL*, OLEA EUROPAEA (OLIVE) OIL*, JOJOBA ESTERS, BUTYROSPERMUM PARKII (SHEA) BUTTER*, EUPHORBIA CERIFERA (CANDELLILLA) WAX, COPERNICIA CERIFERA (CARNAUBA) WAX, CALENDULA OFFICINALIS EXTRACT*, AVENA SATIVA (OAT) KERNEL FLOUR*, ORMENIS MULTICAULIS (WILD CHAMOMILE) OIL*, TOCOPHEROL (ESSENTIAL OIL COMPONENTS: LIMONENE) <small>*Certified organic</small>	
			<b>Questions or Comments?</b> Call 1.800.263.8888 Outside Canada or U.S dial +1514.333.8282 or visit <a href="http://druidebio.com">druidebio.com</a>	
				 Manufactured by Laboratoires Druides Inc. Pointe-Claire, QC H9R 1A8 Canada Distributed by 777 4672 CANADA INC. D&A, Dorval, QC St. Laurent (Qc) H4S 1A7 Canada

## DRUIDE BIOLOVE FOR DIAPER RASH

kaolin paste

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71447-300
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
KAOLIN (UNII: 24H4NWX5CO) (KAOLIN - UNII:24H4NWX5CO)	KAOLIN	4 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
HELIANTHUS ANNUUS FLOWERING TOP (UNII: BKJ0J3D1BP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
AVENA SATIVA TOP (UNII: 1ZX4OXU3N6)	
OLEA EUROPAEA (OLIVE) OIL UNSAPONIFIABLES (UNII: XO45V955LT)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ACMELLA OLERACEA FLOWERING TOP (UNII: 1O11RD9U53)	
SHEA BUTTER (UNII: K49155WL9Y)	
CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9)	
CANDELILLA WAX (UNII: WL0328HX19)	
CALENDULA OFFICINALIS SEED OIL (UNII: 9JS8DS42SV)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71447-300-01	1 in 1 BOX	12/16/2019	
1	NDC:71447-300-00	100 g in 1 TUBE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	12/16/2019	

**Labeler** - LABORATOIRES DRUIDE INC (245815014)**Registrant** - LABORATOIRES DRUIDE INC (245815014)**Establishment**

Name	Address	ID/FEI	Business Operations
LABORATOIRES DRUIDE INC		245815014	manufacture(71447-300)