# ARIELLA HEMORRHOID GEL- phellodendron chinense whole, senegalia catechu wood, sophora flavescens root gel YITONGBADA (SHENZHEN) INTERNATIONAL TRADE 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.

-----

## **Active Ingredient**

## **Purpose**

Cortex Phellodendri 6% Protectant

Acacia Catechu Wood Extract 2% Protectant

Sophora Flavescens Root Extract 12% Vasoconstrictor

#### Uses

helps relieve itching and discomfort associated with hemorrhoids - temporarily shrinks swelling and relieves burning and pain -soothes and protects irritated tissue

## Warnings

For external use only.

**Ask a doctorbefore use if you** have heart disease -high blood pressure - thyroid disease - diabetes -difficulty in urination due to enlargement of the prostate gland

**Ask a doctor or pharmacist before use if you are** presently taking a prescription drug for high blood pressure or depression.

When using this product do not exceed the recommended daily dosage unless directed by a doctor

**Stop and ask a doctor if** - bleeding occurs -condition worsens or does not improve within 7 days introduction of the applicator into the rectum causes additional pain -an allergic reaction occurs - symptom does not improve or if redness, irritation, swelling, pain or other symptoms develop or increase

If pregnant or breast-feeding, ask a health professional before use.

**Keep out of reach of children**. In case of accidental ingestion, seek medical advice immediately or contact a Poison Control Center right away. (1-800-222-1222)

### **Directions**

- when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe.
- Gently dry by patting or blotting with a tissue or a soft cloth before application.
- apply half the gel in the applicator to the external affected area (only applies if you have external symptoms)

- find a comfortable position and gently insert about ½ inch into the rectum.
- push the end of the applicator to apply the remaining gel inside the rectum (Both steps are necessary for both internal and external symptoms as external hemorrhoid often comes with internal hemorrhoid)
- dispose the applicator after use.
- avoid movement for 1-3 hours
- Children under 12 years of age: ask a doctor

## Other information

store at 15-25°C (59-77°F)

## Inactive ingredients

Calamine, Daemonorops Draco Extract, Mentholatum, Glycyrrhiza Glabra, Aqua, Alcohol, Carbomer, Triethanolamine, Ethylparaben

## Questions or comments?

Contact us at www.tryariella.com or email cs@tryariella.com

## Product label

#### ARIELLA HEMORRHOID GEL

#### 6 applicators

NET WT: 3g per Applicator

## Drug Facts

Active ingredients Purpose
Cortex Phellodendri 6% Protectant
Acacia Catechu Wood Extract 2% Protectant
Sophora Flavescens Root Extract 12% Vasoconstrictor

#### Uses

-helps relieve itching and discomfort associated with hemorrhoids - temporarily shrinks swelling and relieves burning and pain -soothes and protects irritated tissue

#### Warnings

For external and/or intrarectal use only

#### Ask a doctor before use if you have

-heart disease -high blood pressure - thyroid disease - diabetes -difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression.

When using this product do not exceed the recommended daily dosage unless directed by a doctor

Stop and ask a doctor if - bleeding occurs -condition worsens or does not improve within 7 days -introduction of the applicator into the rectum causes additional pain -an allergic reaction occurs - symptom does not improve or if redness, irritation, swelling, pain or other symptoms develop or increase

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of accidental ingestion, seek medical advice immediately or contact a Poison Control Center right away. (1-800-222-1222)

#### Directions

- -when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with a tissue or a soft cloth before application.
- -apply half the gel in the applicator to the external affected area (only applies if you have external symptoms)
- -find a comfortable position and gently insert about 1/2 inch into the rectum.
- -push the end of the applicator to apply the remaining gel inside the rectum (Both steps are necessary for both internal and external symptoms as external hemorrhoid often comes with internal hemorrhoid)
   -dispose the applicator after use.
- -avoid movement for 1-3 hours
- -Children under 12 years of age: ask a doctor

Other information store at 15-25°C (59-77°F)

Inactive ingredients Calamine, Daemonorops Draco Extract, Mentholatum, Glycyrrhiza Glabra, Aqua, Alcohol, Carbomer, Triethanolamine, Ethylparaben

Questions or comments? Contact us at www.tryariella.com or email cs@tryariella.com

## ARIELLA HEMORRHOID GEL

phellodendron chinense whole, senegalia catechu wood, sophora flavescens root gel

### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:83364-002

Pouto	of Administration	TOPICAL
Route	of Administration	TOPICAL

Active Ingredient/Active Moiety						
Ingredient Name	<b>Basis of Strength</b>	Strength				
PHELLODENDRON CHINENSE WHOLE (UNII: QKA3ZK8IIE) (PHELLODENDRON CHINENSE WHOLE - UNII:QKA3ZK8IIE)	PHELLODENDRON CHINENSE WHOLE	6 g in 100 g				
SENEGALIA CATECHU WOOD (UNII: CHL342Y4LA) (SENEGALIA CATECHU WOOD - UNII:CHL342Y4LA)	SENEGALIA CATECHU WOOD	2 g in 100 g				
<b>SOPHORA FLAVESCENS ROOT</b> (UNII: IYR6K8KQ5K) (SOPHORA FLAVESCENS ROOT - UNII:IYR6K8KQ5K)	SOPHORA FLAVESCENS ROOT	12 g in 100 g				

Inactive Ingredients			
Ingredient Name	Strength		
ZINC OXIDE (UNII: SOI2LOH54Z)			
CALAMUS DRACO WHOLE (UNII: 1C8HA8O22C)			
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)			
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)			
WATER (UNII: 059QF0KO0R)			
ALCOHOL (UNII: 3K9958V90M)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)			
TROLAMINE (UNII: 903K93S3TK)			
ETHYLPARABEN (UNII: 14255EXE39)			

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:83364-002- 01	6 in 1 BOX	05/17/2023			
1		3 g in 1 TUBE; Type 0: Not a Combination Product				

Marketing Information				
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
	05/17/2023			
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date		

# Labeler - YITONGBADA (SHENZHEN) INTERNATIONAL TRADE CO., LTD (725220463)