MEGABABE BUTT STUFF HEMORRHOIDAL- cocoa butter, glycerin, lidocaine, petrolatum, phenylephrine hydrochloride ointment MEGABABE, LLC

MegaBabe Butt Stuff Hemorrhoidal Ointment

Drug Facts

Active ingredients

Cocoa Butter 12.5%

Glycerin 25%

Lidocaine 5%

Petrolatum 12.5%

Phenylephrine HCL 0.25%

Purposes

Protectant

Local Anesthetic

Vasoconstrictor

Uses:

- Helps relieve the local itching and discomfort in the perianal area.
- Temporarily relieves pain, irritation or burning and reduces the swelling associated with irritated hemorrhoidal tissue and other anorectal disorders.

Warnings:

For external use only.

□ **Allergy alert** • Certain persons can develop allergic reactions to ingredients in this product.

Do not

- Exceed the recommended daily dosage unless directed by a doctor.
- Put this product into the rectum by using fingers or any mechanical device or applicator.
- Use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

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

- If condition worsens or does not improve within 7 days, consult a doctor.
- In case of bleeding, consult a doctor promptly.

Stop use and ask a doctor if

• If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase.

Keep out of reach of children.

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

If pregnant or breastfeeding,

ask a health professional before use.

Directions:

Adults: • When practical, cleanse the affected area with mild soap and warm water and rinse by patting or blotting with an appropriate cleansing pad.

- Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.
- Children under 12 years of age: consult a doctor.
- Apply externally to the affected area up to 4 times daily.

Other Information:

Store at room temperature and away from direct sunlight. Do not use if tamper seal over the tube opening is missing.

Inactive Ingredients:

Aloe Barbadensis Leaf Juice, Aqua (Deionized Water), Ascorbic Acid (Vitamin C), Behentrimonium Methosulfate, Butyrospermum Parkii (Shea) Butter, Calendula Officinalis Extract, Caprylyl Glycol, Carbomer, Cetearyl Alcohol, Cetyl Alcohol, Cocos Nucifera (Coconut) Oil, Colloidal Oatmeal, Cucumis Sativus Extract, Decyl Glucoside, Dimethicone, Glyceryl Laurate, Glyceryl Stearate, Glyceryl Undecylenate, Glycyrrhiza Glabra (Licorice) Root Extract, Hamamelis Virginiana (Witch Hazel) Water, Helianthus Annuus (Sunflower) Seed Oil, Persea Gratissima (Avocado) Oil, Polysorbate 20, Stearic Acid, Stearyl Alcohol, Tetrasodium EDTA, Tocopheryl Acetate (Vitamin E), Xanthan Gum, Propanediol.

Package Labeling:





MEGABABE BUTT STUFF HEMORRHOIDAL

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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84000-502	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
COCOA BUTTER (UNII: 5120YT1CRR) (COCOA BUTTER - UNII:5120YT1CRR)	COCOA BUTTER	125 mg in 1 g
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	250 mg in 1 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	50 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	125 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	
SHEA BUTTER (UNII: K49155WL9Y)	
CALENDULA OFFICINALIS FLOWER (UNII: POM7O4Y7YD)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
COCONUT OIL (UNII: Q9L0O73W7L)	
OATMEAL (UNII: 8PI54V663Y)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
DIMETHICONE (UNII: 92RU3N3Y10)	
GLYCERYL LAURATE (UNII: Y98611C087)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
HAMAMELIS VIRGINIANA TOP WATER (UNII: NT00Y05A2V)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
AVOCADO OIL (UNII: 6VNO72PFC1)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPANEDIOL (UNII: 5965N8W85T)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:84000-502- 00	1 in 1 BOX	06/06/2024		
1		35 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 Drug	M015	06/06/2024		

Labeler - MEGABABE, LLC (081154311)

Revised: 6/2024 MEGABABE, LLC