

BEAUელი- lidocaine cream
EUBIZRIVAL LLC

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.

Active ingredients

Lidocaine 5%

Purpose

Local Anesthetic

Uses

For the temporary relief of local and anorectal itching and discomfort associated with anorectal disorders.

Warnings

For external use only

When using this product

- Do not get into eyes.
- Do not exceed recommend dosage unless directed by doctor.
- Do not put this product into rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days.
- allergic reaction occurs to ingredients in this product.
- symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.
- symptoms clear up and return within a few days.

Keep out of reach of children. If swallowed, get medical help. Do not use if allergic to any ingredients.

If pregnant or breastfeeding ask a health professional before use.

Directions

- When practical clean area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or soft cloth before applying.
- Adults and children 12 years and older: apply externally to the affected area up to 6 times a day.

- Children under 12 years of age: consult a doctor
- To use finger cots: roll one finger cot over finger. Gently squeeze cream on to finger cot. Smooth a layer of the cream.

Other information

Store at room temperature. Avoid direct sunlight. Do not use if temper evident packaging has been breached or is missing.

water, glycerine, Lidocaine Isopropyl palmitate, Aloe barbadensis leaf juice, Retinol, Helianthus annuus (sunflower) seed oil, Glyceryl stearate, Pentylene glycol, Butyrospermum parkii (shea) butter, Cetyl alcohol, Piper methysticum leaf/root/stem extract, Peg-100 stearate, Tocopheryl acetate.

Product label

<p>Drug Facts</p> <hr/> <p>Active Ingredients Lidocaine 5%.....Local Anesthetic</p>
<p>Uses</p> <ul style="list-style-type: none"> For the temporary relief of local and anorectal itching and discomfort associated with anorectal disorders.
<p>Warnings</p> <p>For external use only</p> <p>When using this product</p> <ul style="list-style-type: none"> Do not get into eyes. Do not exceed recommend dosage unless directed by doctor. Do not put this product into rectum by using fingers or any mechanical device or applicator.
<p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> condition worsens or does not improve within 7 days. allergic reaction occurs to ingredients in this product. symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase. symptoms clear up and return within a few days.
<p>Keep out of reach of children. If swallowed, get medical help. Do not use if allergic to any ingredients. If pregnant or breastfeeding ask a health professional before use.</p>
<p>Directions</p> <ul style="list-style-type: none"> When practical clean area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or soft cloth before applying. Adults and children 12 years and older: apply externally to the affected area up to 6 times a day. Children under 12 years of age: consult a doctor To use finger cots: roll one finger cot over finger. Gently squeeze cream on to finger cot. Smooth a layer of the cream.
<p>Other Information</p> <ul style="list-style-type: none"> Store at room temperature. Avoid direct sunlight . Do not use if temper evident packaging has been breached or is missing.
<p>Inactive ingredients water, glycerine, Lidocaine Lsopropyl palmitate, Aloe barbadensis leaf juice, Retinol, Helianthus annuus (sunflower)seed oil, Glyceryl stearate, Pentylene glycol, Butyrospermum parkii (shea)butter, Cetyl alcohol, Piper methysticum leaf/root/stem extract, Peg-100 stearate, Tocopheryl acetate.</p>

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lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83462-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE (UNII: V5VD430YW9)	
SHEA BUTTER (UNII: K49155WL9Y)	
RETINOL (UNII: G2SH0XKK91)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PIPER METHYSTICUM WHOLE (UNII: 3P306S300W)	
PEG-100 STEARATE (UNII: YD01N1999R)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83462-001-01	50 g in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/01/2023	

Labeler - EUbizrival LLC (036572203)**Establishment**

Name	Address	ID/FEI	Business Operations
Guangzhou Pallas Cosmetics Co.,Ltd.		419564106	manufacture(83462-001)

Revised: 8/2023

EUbizrival LLC