

**GLYCERIN, LIDOCAINE, PETROLATUM, AND PHENYLEPHRINE HYDROCHLORIDE-
glycerin, lidocaine, petrolatum, and phenylephrine hydrochloride cream
ONE2ZEE LIMITED LIABILITY COMPANY**

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.

Glycerin, Lidocaine, Petrolatum, and Phenylephrine Hydrochloride

DRUG FACTS:

Active Ingredient:

Glycerin 14.4%
Lidocaine 5%
Phenylephrine HCl 0.25%
White petrolatum 15%

Purpose

- Protectant
- Local anesthetic
- Vasoconstrictor
- Protectant

Uses:

- For temporary relief of pain, soreness and burning
- Helps relieve the local itching and discomfort associated with hemorrhoids
- Temporarily shrinks hemorrhoidal tissue
- Temporarily provides a coating for relief of anorectal discomforts
- Temporarily protects the inflamed irritated anorectal surface to help make bowel movements less painful

Warnings:

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

Directions:

- Adults: 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 applying this cream.
- Apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- Children under 12 years of age: ask a doctor

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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

Inactive Ingredients:

aloe vera leaf, anhydrous citric acid, butylated hydroxyanisole, carboxymethylcellulose sodium, cetyl alcohol, citric acid monohydrate, dexpanthenol, edetate disodium, glyceryl monostearate, methylparaben, mineral oil, laureth-23, steareth-2, steareth-20, propyl gallate, propylene glycol, propylparaben, sodium benzoate, tocopherol, alpha.- tocopherol acetate, xanthan gum, water

Other Information:

Store at 20-25°C (68-77°F) Do not use if tamper evident packaging has been breached or is missing. Distributed by: Wellspring Airmont, NY 10952 U.S.A.

Package Label



GLYCERIN, LIDOCAINE, PETROLATUM, AND PHENYLEPHRINE HYDROCHLORIDE

glycerin, lidocaine, petrolatum, and phenylephrine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55629-051
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Base of

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	144 mg in 1 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	50 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	150 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	2.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DEXPANTHENOL (UNII: 1O6C93RI7Z)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MINERAL OIL (UNII: T5L8T28FGP)	
LAURETH-23 (UNII: N72LMW566G)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-20 (UNII: L0Q8IK9E08)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
TOCOPHEROL (UNII: R0ZB2556P8)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55629-051-04	1 in 1 CARTON	02/08/2021	
1		113 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	part346	02/08/2021	

Registrant - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Establishment

Name	Address	ID/FEI	Business Operations
YASH PHARMACEUTICALS		871409551	manufacture(55629-051) , analysis(55629-051)

Revised: 2/2021

ONE2ZEE LIMITED LIABILITY COMPANY