TOPICAL ANESTHETIC ANORECTAL CREAM NUMB AND NUMBER- lidocaine cream
Dermtech Labs Inc. dba GD Labs

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.

Numb & Number - Topical Anesthetic anorectal cream

Active Ingredient Purpose
Lidocaine 5% ..... Topical Anesthetic

Temporarily relieves local pain and discomfort of anorectal area.

Keep out of reach of Chilren

Stop use and ask your doctor if rectal bleeding occurs, condition worsens or does not improve within 7 days.

- For Rectal use only
- For external use on intact skin only
- Do not use if pregnant or breast-feeding
- Do not exceed the recommended daily dosage unless directded by a doctor
- Avoid contact with eyes and mucous membranes
- You may experience temporary redness or stinging where the product is applied
- If irritation persists, consult your doctor
- Do not put product into the rectum by using fingers or any mechanical device or applicator

- Children 12 and under, consult a physician prior to use
- When practical, clean area with mild soap and water. Rinse thoroughly and gently dry by blotting with tissue or soft cloth before applying.
- Apply to the affected area up to 6 times daily

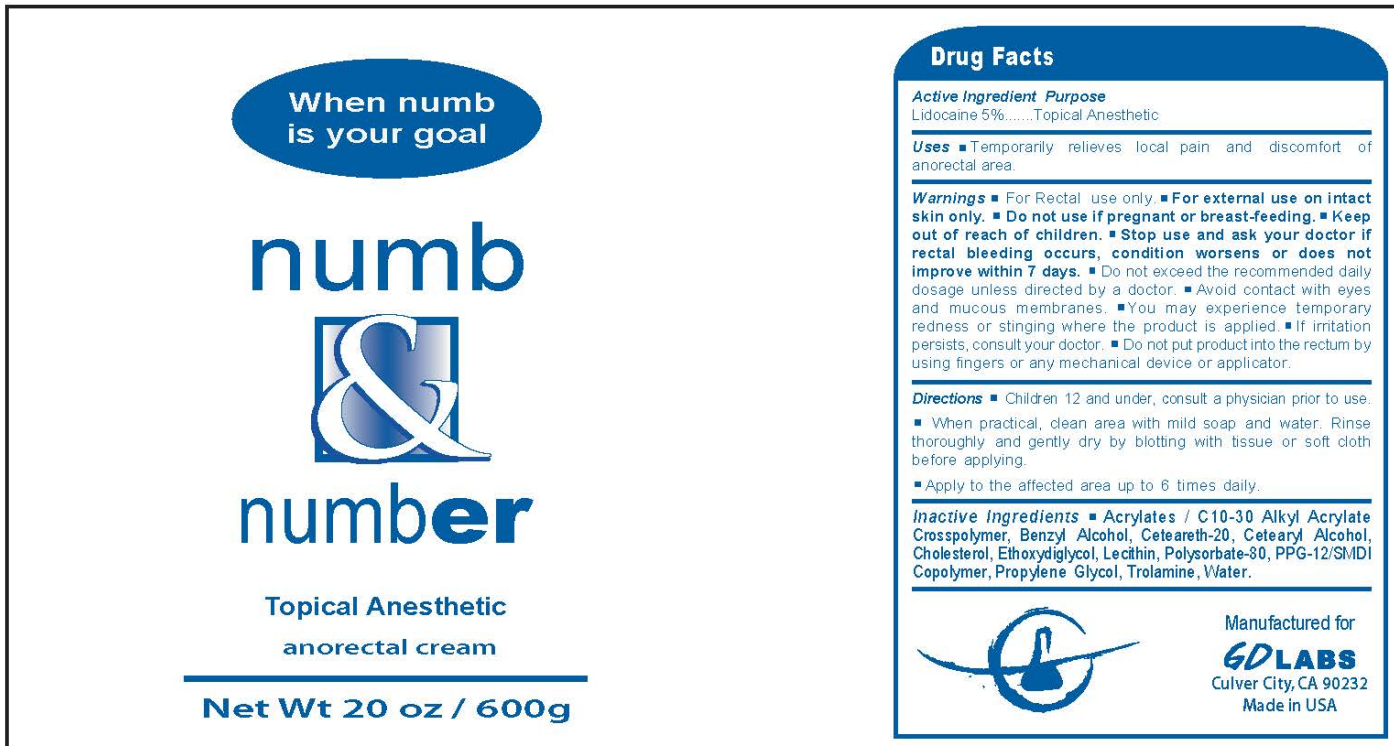
Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Benzyl Alcohol, Ceteareth-20, Cetearyl Alcohol, Cholesterol, Ethoxydiglycol, Lecithin, Polysorbate-80, PPG-12/SMDI Copolyme, Propylene Glycol, Trolamine, Water

Numb & Number

Topical Anesthetic

Anorectal Cream

Net Wt 20 oz / 600g



TOPICAL ANESTHETIC ANORECTAL CREAM NUMB AND NUMBER

lidocaine cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68848-001
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**
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHOLESTEROL (UNII: 97C5T2UQ7J)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
PPG-12/SMDI COPOLYMER (UNII: 1BK9DDD24E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68848-001-02	1 in 1 PACKAGE	08/11/2016	
1	NDC:68848-001-01	54 g in 1 PACKAGE; Type 0: Not a Combination Product		
2	NDC:68848-001-04	1 in 1 PACKAGE	08/11/2016	
2	NDC:68848-001-03	600 g in 1 PACKAGE; 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	08/11/2016	

Labeler - Dermtech Labs Inc. dba GD Labs (148077899)

Registrant - Dermtech Labs Inc. dba GD Labs (148077899)

Establishment

Name	Address	ID/FEI	Business Operations
VEGE-KURL, INC		021072509	manufacture(68848-001)

Revised: 1/2017 Dermtech Labs Inc. dba GD Labs