ANORECTAL WALGREENS- lidocaine cream Walgrrens

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.

Drug Facts

Active ingredient

Purpose

Lidocaine 5%.....Local anesthetic

Uses For temporary relief of pain, soreness and burning.

Warnings For external use only

When using this product do not get into eyes. Stop use and ask a doctor if • condition worsens or does not improve within 7 days • do not exceed the recommended daily dosage unless directed by a doctor

• in case of bleeding, consult a doctor promptly • do not put this product into the rectum by using fingers or any mechanical device or applicator

• certan persons can develop allergic reactions to ingredients in this product. If the simptoms being treated does not subside or if redness, irritation, swelling, or other simproms develop or increase, discontinue use and consult a doctor

Keep out of reach of children. If swallowed, get medical

help or contact a Poison Control Center right away.

Directions Apply externally to affected area up to 6 times daily. Gently dry by patting or blotting with tissue or a soft cloth before application of this product

Other information Store at 25° C (77° F); excursions permitted to 15-30° C (59-86° F).

Inactive ingredients

Benzyl Alcohol, Carbomer 940, Cholesterol, Hydrogenated Lecithin, Isopropyl Myristate, Polysorbate 80, Propylene Glycol, Purified Water, Trolamine, Vitamin E Acetate.



ANORECTAL WALGREENS

lidocaine cream

Product Information						
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-1114			
Route of Administration	TOPICAL					

Active Ingredient/	Active Moiety		
	Ingredient Name	Basis of Streng	th Strength
Lidocaine (UNII: 98PI20	0987) (LIDOCAINE - UNII:98PI200987)	Lidocaine	5 g in 100 mL
Inactive Ingredien	ts		
	Ingredient Name		Strength
Benzyl alcohol (UNII: L	KG8494WBH)		
Carbomer 940 (UNII: 40	Q93RCW27E)		
Cholesterol (UNII: 97C5	T2UQ7J)		
HYDRO GENATED SO Y	BEAN LECITHIN (UNII: H1109Z9J4N)		
Isopropyl Myristate (UN	NII: 0 RE8 K4LNJS)		
Polysorbate 80 (UNII: 6	OZP39ZG8H)		
Propylene Glycol (UNII:	6DC9Q167V3)		
Water (UNII: 059QF0KO	0 R)		
Trolamine (UNII: 903KS	93S3TK)		
ALPHATOCOPHERO	L ACETATE (UNII: 9E8X80D2L0)		
Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Dat
1 NDC:0363-1114-01	in 1 CARTON	03/18/2016	
1 28	3.3 mL in 1 TUBE; Type 0: Not a Combination Product		
Marketing Info	rmation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Dat
OTC monograph final	part346	03/18/2016	

Labeler - Walgrrens (008965063)

Registrant - Product Quest (927768135)

Establishment						
Name	Address	ID/FEI	Business Operations			
Product Quest		927768135	manufacture(0363-1114) , label(0363-1114)			

Revised: 10/2017

Walgrrens