

RECTAEASE HEMORRHOID RELIEF CREAM- lidocaine cream
Trifecta Pharmaceuticals USA LLC

RectaEase Hemorrhoid Relief Cream

Drug Facts

Active Ingredient

Lidocaine 5% w/w

Purpose

Local Anesthetic

Uses

Helps relieve the pain, itching and burning associated with hemorrhoids and other anorectal disorders.

Warning Section

For External Use Only

Stop use and ask a doctor

Rectal bleeding occurs

Condition worsens

Symptoms persist for more than 7 days or clear up and return within a few days

Symptoms being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.

When using this product

Avoid contact with the eyes

do not use more than directed unless told to do so by a doctor

do not put directly into the rectum by using fingers or any mechanical device or applicator

If Pregnant or Breast Feeding

Ask doctor before use

Keep out of reach of children

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

Directions

Directions:

When practical, clean the affected area with mild soaping warm water and rinse thoroughly.

Gently dry by patting or blotting with a toilet tissue or soft cloth before applying.

Adult and children 12 years of age and older, apply to affected area not more than 6 times a day.

Children under 12 years of age: do not use, ask a doctor

Other Information

Store at 20°-25°C (68°-77°F)

Inactive Ingredients

Benzyl alcohol, Carbomer 940, Cholesterol, Hydrogenated Lecithin, Isopropyl myristate, Propylene glycol, Trolamine, Vitamin E, polysorbate 80, propylene glycol, purified water

Questions or Comments

Call 1-888-296-9067

Distributed By

Trifecta Pharmaceuticals USA™

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1-888-296-9067

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Packaging

OUTSIDE BOX

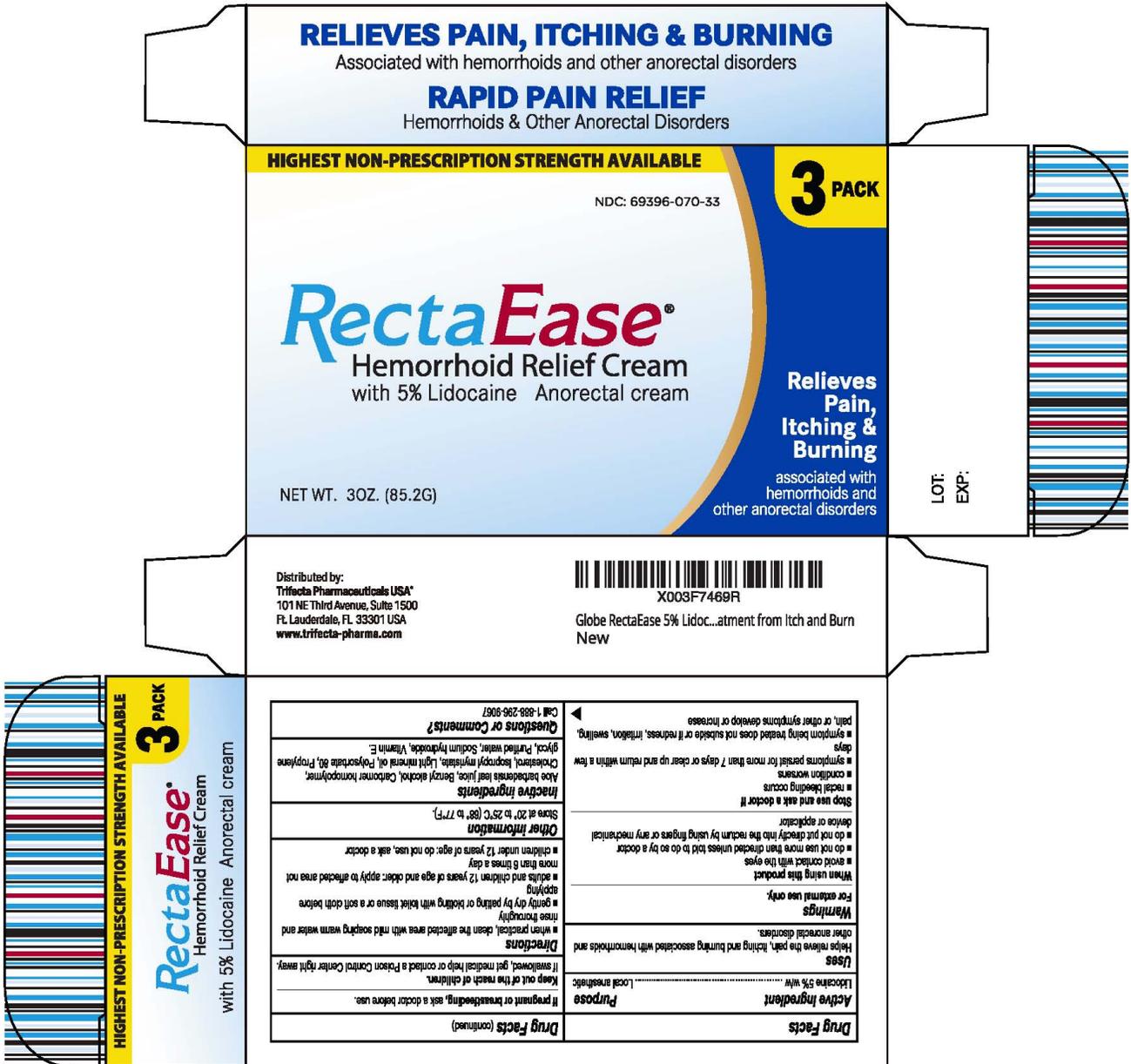


INNER TUBE



Packaging

OUTSIDE BOX



Packaging

OUTSIDE BOX



OUTSIDE BOX



RECTAEASE HEMORRHOID RELIEF CREAM

lidocaine cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-070
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Drug Facts	Drug Facts (continued)
Active ingredient Lidocaine 5% w/w Local anesthetic	Purpose If prurient or breastfeeding, ask a doctor before use.
Uses Lidocaine 5% w/w Local anesthetic	Directions If swollen, get medical help or contact a Poison Control Center right away. When practical, clean the affected area with mild soaping warm water and rinse thoroughly. Apply gently dry by patting or blotting with toilet tissue or a soft cloth before applying. For external use only.
Warnings When using this product: Do not use more than directed unless told to do so by a doctor. Do not use more than directed unless told to do so by a doctor. Do not put directly into the rectum by using fingers or any mechanical device or applicator. Stop use and ask a doctor if: Rectal bleeding occurs Condition worsens Symptoms persist for more than 7 days or clear up and return within a few days Symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase	Other information Store at 20° to 25°C (68° to 77°F). Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
Questions or Comments? Call 1-888-296-9067	Inactive ingredients Aloe barbadensis leaf juice, Benzyl alcohol, Carbomer homopolymer, Croscellose, Isopropyl myristate, Light mineral oil, Polyacrylate 90, Propylene glycol, Purified water, Sodium hydroxide, Vitamin E.

Ingredient Name		Basis of Strength	Strength	
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)		LIDOCAINE	50 mg in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
CHOLESTEROL (UNII: 97C5T2UQ7J)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
LIGHT MINERAL OIL (UNII: N6K5787QVP)				
ALOE BARBADENSIS LEAF JUICE (UNII: RUE8E6T4NB)				
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-070-01	1 in 1 BOX	04/19/2021	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69396-070-22	2 in 1 BOX	03/04/2026	
2		28 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:69396-070-33	3 in 1 BOX	03/04/2026	
3		28 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	04/19/2021		

Labeler - Trifecta Pharmaceuticals USA LLC (079424163)