TUCKS MULTI-CARE RELIEF KIT (TUCKS HEMORRHOIDAL AND TUCKS MEDICATED COOLING 40 COUNT)- glycerin, lidocaine, and witch hazel Blistex Inc

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.

Tucks[®] Multi-Care Relief Kit (Tucks[®] Hemorrhoidal Cream and Tucks[®] Medicated Cooling Pads 40 Count)

Tucks® Hemorrhoidal Cream

Drug Facts

Active ingredients	Purpose
Glycerin 15.0% (w/w)	Protectant
Lidocaine 5.0% (w/w)	Local anesthetic

Uses

- temporarily relieves the local pain, itching and discomfort associated with hemorrhoids
- temporarily provides a coating for relief of anorectal discomforts
- temporarily relieves rectal irritation and burning

Warnings

For external use only

When using this product

- do not exceed the recommended daily dosage unless directed to do so by a doctor
- do not put directly in the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- rectal bleeding occurs
- condition worsens or does not improve within 7 days
- certain persons can develop allergic reactions to ingredients in this product. If the symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms 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

Adults:

- when practical, clean the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before applying
- apply externally to the affected area up to 6 times daily or after each bowel movement

Children under 12 years of age: ask a doctor

Inactive ingredients

arachidyl alcohol, arachidyl glucoside, avena sativa kernel flour (colloidal oatmeal), behenyl alcohol, disodium EDTA, ethylhexylglycerin, microcrystalline wax, petrolatum, phenoxyethanol, polyglyceryl-3 diisostearate, polysorbate 60, purified water, sorbitan isostearate, stearyl behenate

Tucks® **Medicated Cooling Pads**

Drug Facts

Active ingredient

Witch hazel (50% v/v)

Purpose

Astringent

Uses

- temporarily relieves the local itching and discomfort associated with hemorrhoids
- aids in protecting irritated anorectal areas
- temporarily relieves irritation and burning

Warnings

For external use only

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Adults:

- when practical, clean the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before applying
- apply externally to the affected area up to 6 times daily or after each bowel movement
- after application, discard pad and wash hands

Children under 12 years of age: ask a doctor

Other information

• for use as a moist compress — if necessary, first cleanse the area and place wipe in contact with irritated area for a soothing and cooling effect. Leave in place for up to 15 minutes and repeat as needed but not to exceed directions for use

Inactive ingredients

citric acid, diazolidinyl urea, glycerin, methylparaben, propylene glycol, propylparaben, purified water, sodium citrate

PRINCIPAL DISPLAY PANEL - Kit Carton

TUCKS®

New

MULTI-CARE RELIEF KIT

Cream: Local Anesthetic / Protectant

Pads: Astringent

Lidocaine 5% Cream to numb & protect painful hemorrhoids

+

Witch Hazel Pads to cleanse & soothe rectal or vaginal areas

 $TUCKS^{\circledR}$

HEMORRHOIDAL CREAM MAXIMUM STRENGTH LIDOCAINE

with

Colloidal

Oatmeal

TUCKS®

MEDICATED COOLING PADS

WITH WITCH HAZEL

40 PADS

with

Ultra-soft

Fabric

Net Wt. 0.5 oz.

(14 g) - 1 Tube

2-Product Value

40 Pads

1 Jar

TUCKS

TUCKS

Drug Facts

Active ingredient Witch hazel (50% v/v)....

Purpose

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Inactive ingredients

ethylparaben, propylene glycol, opylparaben, purified water, sodium citrate

TUCKS

New

MULTI-CARE RELIEF KIT

Cream: Local Anesthetic / Protectant Pads: Astringent

Lidocaine 5% Cream witch Hazel Pads to cleanse a soothe painful hemorrhoids



to cleanse & soothe rectal or vaginal areas



Net Wt. 0.5 oz. (14 g) - 1 Tube

2-Product Value

40 Pads

TUCKS

WHAT YOU NEED, WHEN YOU NEED IT.

Witch Hazel Pads

For relief from rectal or vaginal discomfort, burning and itching, Tucks pads - the #1 witch hazel pads in America - gently cleanse and soothe sensitive areas.

5% Lidocaine Cream

or severe rectal pain, Tucks lidocaine 5% cream with soothing colloidal oatmeal provides rapid relief and protects sore, raw skin from irritation.



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GUARANTEED P.O. Box 5392
Distex Cook Brook, IL 60522-5392
#C030180

Carton is 100% Recyclable.

No Copy No Varnish

olysorbate 60, purified water, sorbitan isostearate, stearyl behenate EDTA, ethylhexylglycerin, microcrystalline wax, petrolatum, phenoxyethanol, polyglyceryl-3 disostearate, rachidyl alcohol, arachidyl glucoside, avena sativa kernel flour (colloidal oatmeal), behenyl alcohol, disodium Inactive ingredients

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TUCKS MULTI-CARE RELIEF KIT (TUCKS HEMORRHOIDAL AND TUCKS MEDICATED COOLING 40 COUNT)

glycerin, lidocaine, and witch hazel kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:10157-2112

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:10157-2112-1	1 in 1 CARTON	0 2/15/20 19	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	14 g
Part 2	1 APPLICATOR	1 mL

Part 1 of 2

TUCKS HEMORRHOIDAL

glycerin, and lidocaine cream

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	15 g in 100 g
LIDO CAINE (UNII: 98PI200987) (LIDO CAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

PETROLATUM (UNII: 4T6H12BN9U)	
MICRO CRYSTALLINE WAX (UNII: XOF597Q3KY)	
STEARYL BEHENATE (UNII: A68S9UI39D)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ARACHIDYL ALCOHOL (UNII: 1QR1QRA9BU)	
DOCOSANOL (UNII: 9G10E216XY)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46 P231IQV8)	
OATMEAL (UNII: 8PI54V663Y)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		14 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information				
Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing En				
OTC MONOGRAPH FINAL	part346	0 2/15/20 19		

Part 2 of 2

TUCKS MEDICATED COOLING

witch hazel solution

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety Ingredient Name Basis of Strength

Ingredient NameBasis of StrengthStrengthWITCH HAZEL (UNII: 10 114J0 U34) (WITCH HAZEL - UNII: 10 114J0 U34)WITCH HAZEL500 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1	1 mL in 1 APPLICATOR; 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	0 2/15/20 19		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part346	02/15/2019			

Labeler - Blistex Inc (005126354)

Establishment				
Name	Address	ID/FEI	Business Operations	
Blistex Inc		005126354	MANUFACTURE(10157-2112)	

Revised: 12/2018 Blistex Inc