

**MYDERM- penylephrine hci, witch hazel, lidocaine hcl, spray
Inspec Solution LLC.**

MyDerm Medical 5% Lidocain Numbing Spray

Active ingerdients

Witch Hazel Distillate 42.50%

Lidocaine HCl 5.00%

Penylephrine HCl 0.25%

Purpose

Witch Hazel DistillateAnesthetic

Lidocaine HCl 5.00%Anesthetic

Penylephrine HCl 0.25%Vasoconstrictor

Uses

Uses: Temporary shrinks hemorrhoidal tissue •Temporarily reduces swelling associated with irritated anorectal areas.

Warning

For external use only

When using this product

When using this product • avoid spraying in eye• content under pressure •do not puncture or incinerate •do not store at temperature above 120° F •do not exceed recommended daily dosage unless directed by doctor •do not put this product into rectum by using fingers or any mechanical device or applicator

Ask a doctor or pharmacist

Ask a doctor or pharmacist before use if you have • heart disease, high blood pressure, thyroid disease, diabetes, difficulty in urination due to enlargement of prostate gland •are presently taking a prescription drug or high blood pressure or depression.

Stop use and ask doctor

Stop use and ask doctor if • condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur again within a few days

If pregnant or breast-feeding

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

Keep out of reach of children

Keep out of reach of children • If swallowed, get medical help or contact a Poison Control Center immediately

Directions

Directions • For adults and children 12 years of age and older: Apply to affected area not more than 3 to 4 times daily • Children under 2 years of age: consult physician.

Question?

Question? 1-855-myderm1

Inactive Ingredient

Alcohol

Aloe Barbadensis Leaf

Benzophenone-4

Disodium EDTA

Tocopheryl Acetate

Ethylhexylglycerin

Phenoxyethanol

Polysorbate-20

Propylene Glycol

Sodium Citrate

Water

myDerm™
MEDICAL

5% LIDOCAINE
NUMBING
SPRAY

- Fast-acting Topical Anesthetic
- Child Resistant Packaging
- No-touch Application
- Sprays at any Angle

TRUE Maximum
Strength

NET WT. 4.5 OZ (127 g)

Drug Facts	
Active ingredients	Purpose
Witch Hazel Extract 42.50%	Anesthetic
Lidocaine HCl 5%	Anesthetic
Phenylephrine Hydrochloride 0.25%	Vasoconstrictor
Uses Temporarily shrinks hemorrhoidal tissue. • Temporarily reduces swelling associated with irritation • Helps protect irritated anorectal areas.	
Warnings For external use only.	
When using this product • avoid spraying in eyes. • contents under pressure. • do not puncture or incinerate. • do not store at temperature above 120° F. • do not exceed recommended daily dosage unless directed by doctor. • do not put this product into rectum by using fingers or any mechanical device or applicator.	
Ask a doctor or pharmacist before use if you have • heart disease, high blood pressure, thyroid disease, diabetes, difficulty in urination due to enlargement of prostate gland. • are presently taking a prescription drug for high blood pressure or depression.	
Stop use and ask doctor if • condition worsens, or if symptoms persist for more than 7 days, or clear up and reoccur again within a few days.	
If pregnant or breastfeeding , ask a healthcare professional before use.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.	
Directions • Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. • Children under 2 years of age: Consult physician.	
Inactive ingredients Alcohol, Aloe Barbadensis Leaf, Benzophenone-4, Disodium EDTA, Tocopheryl Acetate, Ethylhexylglycerin, Phenoxethanol, Polysorbate-20, Propylene Glycol, Sodium Citrate, Water.	
Questions? 1-855-MYDERM1	



Distributed by: myDerm
Daytona Beach, FL 32117
1-855-MYDERM1
www.myderm.com



MYDERM

phenylephrine hci, witch hazel, lidocaine hcl, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72667-081
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 g
LIDOCAINE (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE	5 g in 100 g
HAMAMELIS VIRGINIANA (WITCH HAZEL) LEAF WATER (UNII: 8FP93ED6H2) (HAMAMELIS VIRGINIANA (WITCH HAZEL) LEAF WATER - UNII:8FP93ED6H2)	HAMAMELIS VIRGINIANA (WITCH HAZEL) LEAF WATER	42.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

ALCOHOL (UNII: 3K9958V90M)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
BENZOPHENONE-4 (UNII: 1W6L629B4K)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
ALOE BARBADENSIS LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DISODIUM HYDROGEN CITRATE (UNII: 6FO62KCQ7A)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72667-081-01	127 g in 1 CAN; Type 0: Not a Combination Product	11/04/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	11/04/2024	

Labeler - Inspec Solution LLC. (081030372)

Establishment

Name	Address	ID/FEI	Business Operations
Inspec Solutions LLC.		081030372	manufacture(72667-081)

Revised: 11/2024

Inspec Solution LLC.