THE SOLUTION NUMBING- lidocaine hydrochloride gel SCALP TECH INC

SCALP TECH (as PLD) - THE SOLUTION NUMBING GEL (82617-105)

ACTIVE INGREDIENTS

LIDOCAINE HYDROCHLORIDE 5%

PURPOSE

LOCAL ANESTHETICS

USES

- FOR THE TEMPORARY RELIEF OF DISCOMFORT AND ITCHING IN THE PERIANAL AREA HEMORRHOIDS, ANORECTAL DISORDERS, INFLAMED HEMORRHOIDAL TISSUES, ANORECTAL INFLAMMATION, HEMORRHOIDAL TISSUES OR PILES
- PAIN
- SORENESS
- BURNING

WARNINGS

STOP USE AND ASK A DOCTOR IF

CONDITION WORSENS OR DOES NOT IMPROVE WITHIN 7 DAYS, CONSULT A
PHYSICIAN; DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE, UNLESS
DIRECTED BY A PHYSICIAN; IN CASE OF BLEEDING, CONSULT A PHYSICIAN
PROMPTLY; DO NOT PUT THIS PRODUCT INTO THE RECTUM BY USING FINGERS OR
ANY MECHANICAL DEVICE OR APPLICATOR. 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
PHYSICIAN.

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED, CALL A POISON CONTROL CENTRE OR GET MEDICAL HELP RIGHT AWAY.

DIRECTIONS

- ADULT
- CLEANSE THE AFFECTED AREA WITH: MILD SOAP AND WARM WATER AND RINSE THOROUGHLY/BY PATTING OR BLOTTING WITH AN APPROPRIATE CLEANSING PAD.
- GENTLY DRY BY PATTING OR BLOTTING WITH TOILET TISSUE OR A SOFT CLOTH BEFORE APPLICATION OF THIS PRODUCT
- CHILDREN UNDER 12 YEARS OF AGE: CONSULT A PHYSICIAN
- APPLY EXTERNALLY TO THE AFFECTED AREA UP TO 6 TIMES DAILY

- DO NOT USE MORE OFTEN THAN DIRECTED
- GENTLY APPLY TO THE AFFECTED AREA BY PATTING AND THEN DISCARD (PAD)

OTHER INFORMATION

STORE AT ROOM TEMPERATURE (15° - 30°C)

INACTIVE INGREDIENTS

WATER/AQUA, ALCOHOL DENAT, PROPANEDIOL, ETHOXYDIGLYCOL, CARBOMER, TRIETHANOLAMINE, PHENOXYETHANOL, ETHYLHEXYLGLYCERIN

QUESTIONS?

CALL - 1 (403) 901-8244



Drug Facts

Active ingredient

Lidocaine hydrochloride 5% ...

Purpose Local Anesthetic

Uses • for the temporary relief of discomfort and itching in the perianal area hemorrhoids, anorectal disorders, inflamed hemorrhoidal tissues, anorectal inflammation, hemorrhoidal tissues or piles • pain • soreness • burning

Warnings

Stop use and ask a doctor if • condition worsens or does not improve within 7 days, consult a physician; do not exceed the recommended daily dosage, unless directed by a physician; in case of bleeding, consult a physician promptly; do not put this product into the rectum by using fingers or any mechanical device or applicator, 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 physician

Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away

Directions

Adult • Cleanse the affected area with: mild soap and warm water
and rinse thoroughly/by patting or blotting with an appropriate
cleansing pad. • Gently dry by patting or blotting with toilet tissue
or a soft cloth before application of this product • children under
12 years of age: consult a physician • apply externally to the
affected area up to 6 times daily • do not use more often than
directed • gently apply to the affected area by patting and then
discard (pad)

Other information

Store at room temperature (15° - 30°C)

Inactive ingredients

Water/Aqua, Alcohol Denat, Propanediol, Ethoxydiglycol, Carbomer, Triethanolamine, Phenoxyethanol, Ethylhexylglycerin

Questions ? + 1 (403) 901 8244

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DIN: XXXXXXXX NDC: 82617-XXX-XX

THE SOLUTION NUMBING

lidocaine hydrochloride gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82617-105

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - LIDOCAINE HYDROCHLORIDE 5 q

UNII:98PI200987)	ANHYDROUS	in 100 mL
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Inactive Ingredients			
Ingredient Name	Strength		
TROLAMINE (UNII: 903K93S3TK)			
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)			
ALCOHOL (UNII: 3K9958V90M)			
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)			
WATER (UNII: 059QF0KO0R)			
ALLANTOIN (UNII: 344S277G0Z)			
PROPANEDIOL (UNII: 5965N8W85T)			
CARBOMER 934 (UNII: Z135WT9208)			
PHENOXYETHANOL (UNII: HIE492ZZ3T)			

l	P	Packaging					
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1	NDC:82617-105- 60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/12/2024			

Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M017	05/12/2024		

Labeler - SCALP TECH INC (200711913)

Revised: 5/2024 SCALP TECH INC