

THE SOLUTION- lidocaine hydrochloride, epinephrine hydrochloride spray
SCALP TECH 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.

SCALP TECH - THE SOLUTION (82617-101)

ACTIVE INGREDIENTS

LIDOCAINE HCL 5%

EPINEPHRINE HCL .01%

PURPOSE

LOCAL ANESTHETICS

VASOCONSTRICTOR

USES

FOR THE TEMPORARY RELIEF OF LOCAL AND ANORECTAL ITCHING, DISCOMFORT, AND PAIN ASSOCIATED WITH ANORECTAL DISORDERS OR ANORECTAL INFLAMMATION.

WARNINGS

- FOR EXTERNAL USE ONLY.
- AVOID CONTACT WITH THE EYES.

KEEP OUT OF REACH OF CHILDREN.

DO NOT USE THIS PRODUCT IF:

- PREGNANT OR BREASTFEEDING, ASK A HEALTH PROFESSIONAL BEFORE USE.
- TAMPER EVIDENT "DO NOT USE THIS PRODUCT" IF SAFETY SEAL IS BROKEN OR MISSING.
- YOU HAVE A HEART CONDITION, HIGH BLOOD PRESSURE, THYROID DISEASE, DIABETES, OR DIFFICULTY IN URINATION DUE TO ENLARGEMENT OF PROSTATE GLAND UNLESS DIRECTED BY A DOCTOR.

WHEN USING THIS PRODUCT:

- DO NOT EXCEED THE RECOMMENDED DAILY USAGE.
- CERTAIN PERSONS CAN DEVELOP ALLERGIC REACTIONS TO INGREDIENTS IN THIS PRODUCT.
- DO NOT PUT THIS PRODUCT INTO THE RECTUM BY USING FINGERS OR ANY MEDICAL DEVICE OR APPLICATOR.

- IF SWALLOWED, CALL YOUR POISON CONTROL CENTER AT 1(800)222-1222.
- IF CONDITION WORSENS OR DOES NOT IMPROVE WITHIN 7 DAYS, CONSULT A DOCTOR.

STOP USE AND ASK A DOCTOR IF:

- THE SYMPTOM BEING TREATED DOES NOT SUBSIDE, OR REDNESS, IRRITATION, SWELLING, PAIN, OR OTHER SYMPTOMS DEVELOP OR INCREASE.

DIRECTIONS

- CLEAN THE AFFECTED AREA.
- SENSITIVITY AND POSSIBLE ALLERGY TESTS ADVISED PRIOR TO USE. SPRAY SPARINGLY TO AFFECTED AREA AFTER THOROUGHLY CLEANSING. WAIT UNTIL ANESTHETIC EFFECT OCCURS. YOU MAY REAPPLY TO CONTINUE NUMBING AFFECT.
- APPLY TO THE AFFECTED AREA UP TO 4 TIMES DAILY.
- CHILDREN UNDER 12 YEARS OF AGE, CONSULT A DOCTOR.

OTHER INFORMATION

- STORE IN COOL DARK PLACE OR REFRIGERATE.
- KEEP AWAY FROM DIRECT SUNLIGHT OR HEAT.
- DISCARD AFTER EXPIRATION DATE.

INACTIVE INGREDIENTS

ALLANTOIN, CAPRYLHYDOXAMIC ACID, ETHOXYDIGLYCOL, 1,2-HEXANEDIOL, PROPANEDIOL, WATER

QUESTIONS?

CALL - 1 (403) 901-8244



4 fl.oz 118 mL

Anorectal Spray

Drug Facts

Active Ingredients	Purpose
Lidocaine HCL 5%.....	Local Anesthetics
Epinephrine HCL .01%.....	Vasoconstrictor

Uses :For the temporary relief of local and anorectal itching, discomfort, and pain associated with anorectal disorders or anorectal inflammation.

Warnings:

- For external use only. • Avoid contact with the eyes.
- Keep out of reach of children.

Do not use this product if:

- Pregnant or breastfeeding, ask a health professional before use.
- Tamper Evident "Do not use this product" if safety seal is broken or missing.
- You have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of prostate gland unless directed by a doctor.

When using this product:

- Do not exceed the recommended daily usage.
- Certain persons can develop allergic reactions to ingredients in this product.
- Do not put this product into the rectum by using fingers or any medical device or applicator.
- If swallowed, call your Poison Control Center at 1(800) 222-1222.
- If condition worsens or does not improve within 7 days, consult a doctor.

Stop use and ask a doctor if:

- The symptom being treated does not subside, or redness, irritation, swelling, pain, or other symptoms develop or increase.

Directions:

- Clean the affected area.
- Sensitivity and possible allergy tests advised prior to use. Spray sparingly to affected area after thoroughly cleansing. Wait until anesthetic effect occurs. You may reapply to continue numbing effect.
- Apply to the affected area up to 4 times daily.
- Children under 12 years of age, consult a doctor.

Other Information:

- Store in cool dark place or refrigerate.
- Keep away from direct sunlight or heat.
- Discard after expiration date.

Inactive Ingredients :

Allantoin, Caprylhydroxamic Acid, Ethoxydiglycol, 1,2-Hexanediol, Propanediol, Water

Questions? Call - 1 (403) 901-8244

THE SOLUTION

lidocaine hydrochloride, epinephrine hydrochloride spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82617-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5 g in 100 mL
EPINEPHRINE HYDROCHLORIDE (UNII: WBB0470038) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE HYDROCHLORIDE	0.01 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
WATER (UNII: 059QF0KO0R)	
ALLANTOIN (UNII: 344S277G0Z)	
PROPANEDIOL (UNII: 5965N8W85T)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82617-101-14	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M015	04/01/2022	

Labeler - SCALP TECH INC (200711913)

Revised: 7/2022

SCALP TECH INC