

**THE SOLUTION- lidocaine hydrochloride, epinephrine hydrochloride spray**  
**SCALP TECH INC**

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**SCALP TECH (as PLD) - 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**

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

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	5 g in 100 mL
<b>EPINEPHRINE HYDROCHLORIDE</b> (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 Drug	M015	04/01/2022	

**Labeler** - SCALP TECH INC (200711913)

Revised: 9/2023

SCALP TECH INC