

GOLD LABEL B NUMB- lidocaine hydrochloride, epinephrine hydrochloride spray
SCALP TECH INC

SCALP TECH (as PLD) - GOLD LABEL - B NUMB (82617-104)

ACTIVE INGREDIENT

LIDOCAINE HCL 5%

EPINEPHRINE (SUPPLIED AS EPINEPHRINE HYDROCHLORIDE) 0.01%

PURPOSE

LOCAL ANESTHETIC

USES

TEMPORARILY RELIEVES SYMPTOMS DUE TO HEMORRHOIDS, HEMORRHOIDAL TISSUES OR PILES:

- ITCHING
- PAIN
- SORENESS
- BURNING

WARNINGS

FOR EXTERNAL USE ONLY.

ASK A DOCTOR OR PHARMACIST BEFORE USE IF YOU HAVE

- HEART DISEASE
- HIGH BLOOD PLESSURE
- THYROID DISEASE
- DIABETES
- DIFFICULTY IN URINATION
- TAKE MEDICINE FOR
- HIGH BLOOD PRESSURE
- DEPRESSION

WHEN USING THIS PRODUCT DO NOT PUT INTO THE RECTUM BY USING FINGERS OR ANY MECHANICAL DEVICE OR APPLICATOR.

STOP USE AND ASK A DOCTOR IF

- BLEEDING OCCURS
- CONDITION WORSENS OR DOES NOT IMPROVE WITHIN 7 DAYS
- REDNESS, IRRITATION, SWELLING, PAIN OR OTHER SYMPTOMS OCCUR
- YOU EXPERIENCE
- WEAKNESS
- CONFUSION
- HEADACHE
- DIFFICULTY BREATHING
- PALE, GREY OR BLUE COLOURED SKIN.

THESE MIGHT BE SIGNS OF METHEMOGLOBINEMIA, A RARE DISORDER, WHICH MAY APPEAR UP TO 2 HOURS AFTER USE.

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

DIRECTIONS

ADULTS AND CHILDREN 12 YEARS AND OVER

- CLEANSE THE AFFECTED AREA WITH MILD SOAP AND WARM WATER
- RINSE WELL OR PAT WITH AN APPROPRIATE CLEANSING PAD

- GENTLY DRY BY PATTING OR BLOTTING WITH TOILET TISSUE OR A SOFT CLOTH BEFORE APPLYING THIS PRODUCT
- USE SPRAY PUMP TO APPLY EXTERNALLY TO THE AFFECTED AREA UP TO 4 TIMES DAILY
- DO NOT USE MORE OFTEN THAN DIRECTED

OTHER INFORMATION

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

INACTIVE INGREDIENTS

AQUA, ETHOXYDIGLYCOL, PHENOXYETHANOL, ALLANTOIN, ETHYLHEXYLGLYCERIN

QUESTIONS?

1 (800) 611-7720

GOLD LABEL B NUMB				
lidocaine hydrochloride, epinephrine hydrochloride spray				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82617-104	
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: WBB0470O38) (EPINEPHRINE - UNII:YKH834O4BH)	EPINEPHRINE HYDROCHLORIDE	0.01 g in 100 mL		
Inactive Ingredients				
Ingredient Name	Strength			
PHENOXYETHANOL (UNII: HIE492ZZ3T)				
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)				
WATER (UNII: 059QF0K00R)				
ALLANTOIN (UNII: 344S277G0Z)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82617-104-59	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	02/22/2024	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M015	02/23/2023		

Labeler - SCALP TECH INC (200711913)