BLACK LABEL B NUMB- lidocaine hydrochloride spray SCALP TECH INC

SCALP TECH (as PLD) - BLACK LABEL - B NUMB (82617-103)

ACTIVE INGREDIENT

LIDOCAINE HCL 5%

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

BLACK LABEL B NUMB

lidocaine hydrochloride spray

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:82617-103

Route of Administration TOPICAL

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name Strength
PHENOXYETHANOL (UNII: HIE492ZZ3T)

DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)

WATER (UNII: 059QF0KO0R)
ALLANTOIN (UNII: 344S277G0Z)

ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)

Packaging

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:82617-103-59	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)

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