

TINA DAVIES ICECREAM- lidocaine hydrochloride, phenylephrine hydrochloride cream
TINA DAVIES PROFESSIONAL LLC

tina davies IceCream

Drug Facts

Active ingredients

Lidocaine HCl 5%

Phenylephrine HCl 0.25%

Purpose

Local anesthetic

Vasoconstrictor

Uses

- For the temporary relief of anorectal itching and discomfort associated with hemorrhoids.
- For temporary relief of pain.

Warnings

For external use only

Allergy alert:

Certain persons can develop allergic reactions to ingredients in this product. The symptom being treated does not subside or if redness, irritation, swelling, pain, or other symptoms develop or increase, discontinue use and consult a doctor.

Ask a doctor before use if

- you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland.

Ask a doctor or pharmacist before use if you

- are presently taking a prescription drug for high blood pressure or depression.

When using this product

- do not exceed the recommended daily dosage unless directed by a doctor.
- do not put this product into the rectum by using fingers or any mechanical device or applicator.

Stop use and ask a doctor if

- Condition worsens or does not improve within 7 days.
- Bleeding occurs.

Keep out of reach of children. If swallowed, get medical help or contact a Poison

Control Center right away.

Directions

- Adults: When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.
- Apply externally to the affected area up to 4 times daily.
- Children under 12 years of age: consult a doctor.

Inactive ingredients

Acetyl Hexapeptide-8, Butylene Glycol, Carboxymethyl Cellulose 2500, Chloroxylenol, Hexanediol CG, Pentapeptide-18, Phenoxyethanol, Ethylhexylglycerin, Polyacrylamide, C13-14 Isoparaffin, Laureth-7, Propylene Glycol, Sodium Hyaluronate, Water (Aqua).

2-in-1 Maximum

Strength Formula

Hemorrhoidal cream

with vasoconstrictor

and local anesthetic

Manufactured for **Tina Davies Professional LLC**

1020 Holland Drive, Unit

109 Boca Raton, FL 33487

1-888-510-1388

tinadavies.com

Packaging

2-in-1 Maximum Strength Formula

tina davies



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IceCream™

Hemorrhoidal cream with vasoconstrictor and local anesthetic

1.0 fl oz (30 mL)

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*2-in-1 Maximum
Strength Formula*

tina
davies

IceCream™

**Hemorrhoidal cream
with vasoconstrictor
and local anesthetic**

1.0 fl oz (30 mL)



THIS UNIT NOT LABELED FOR RETAIL SALE

ACTIVE INGREDIENTS LIDOCAINE HCL 5%, PHENYLEPHRINE HCL 0.25%
PURPOSES LOCAL ANESTHETIC, VASOCONSTRICTOR USES • FOR THE
TEMPORARY RELIEF OF ANORECTAL ITCHING AND DISCOMFORT ASSOCIATED
WITH HEMORRHOIDS. • FOR TEMPORARY RELIEF OF PAIN. WARNINGS FOR
EXTERNAL USE ONLY. ALLERGY ALERT: CERTAIN PERSONS CAN DEVELOP
ALLERGIC REACTIONS TO INGREDIENTS IN THIS PRODUCT, THE SYMPTOM
BEING TREATED DOES NOT SUBSIDE OR IF REDNESS, IRRITATION, SWELLING,
PAIN, OR OTHER SYMPTOMS DEVELOP OR INCREASE, DISCONTINUE USE AND
CONSULT A DOCTOR. ASK A DOCTOR BEFORE USE IF • YOU HAVE HEART
DISEASE, HIGH BLOOD PRESSURE, THYROID DISEASE, DIABETES, OR
DIFFICULTY IN URINATION DUE TO ENLARGEMENT OF THE PROSTATE
GLAND UNLESS DIRECTED BY A DOCTOR. ASK A DOCTOR OR PHARMACIST
BEFORE USE IF YOU • ARE PRESENTLY TAKING A PRESCRIPTION DRUG
FOR HIGH BLOOD PRESSURE OR DEPRESSION. WHEN USING THIS
PRODUCT • DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE
UNLESS DIRECTED BY A DOCTOR. • DO NOT PUT THIS PRODUCT INTO
THE RECTUM BY USING FINGERS OR ANY MECHANICAL DEVICE OR
APPLICATOR. STOP USE AND ASK A DOCTOR IF • CONDITION WORSENS
OR DOES NOT IMPROVE WITHIN 7 DAYS. • BLEEDING OCCURS. KEEP
OUT OF REACH OF CHILDREN. IF SWALLOWED, GET MEDICAL HELP
OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.
DIRECTIONS • ADULTS: WHEN PRACTICAL, CLEANSE THE AFFECTED
AREA WITH MILD SOAP AND WARM WATER AND RINSE
THOROUGHLY. GENTLY DRY BY PATTING OR BLOTting WITH
TOILET TISSUE OR A SOFT CLOTH BEFORE APPLICATION OF THIS
PRODUCT. • APPLY EXTERNALLY TO THE AFFECTED AREA UP TO 4
TIMES DAILY. • CHILDREN UNDER 12 YEARS OF AGE: CONSULT A
DOCTOR.

**Manufactured for Tina
Davies Professional LLC**
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lidocaine hydrochloride, phenylephrine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84313-001
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	0.25 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ACETYL HEXAPEPTIDE-8 AMIDE (UNII: L4EL31FWL)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CARBOXYMETHYLCELLULOSE CALCIUM (UNII: UTY7PDF93L)	
CHLOROXYLENOL (UNII: 0F32U78V2Q)	
HEXANEDIOL (UNII: ZIA319275I)	
PENTAPEPTIDE-18 (UNII: PO4D55T1IG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
POLYACRYLAMIDE (10000 MW) (UNII: E2KR9C9V2I)	
C12-14 ISOPARAFFIN (UNII: WP37Z9V66A)	
LAURETH-7 (UNII: Z95S6G8201)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84313-001-30	1 in 1 CARTON	06/12/2024	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:84313-001-05	5 mL in 1 TUBE; Type 0: Not a Combination Product	06/12/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	06/12/2024	

Labeler - TINA DAVIES PROFESSIONAL LLC (119265327)

Establishment

Name	Address	ID/FEI	Business Operations
THE SKINCARE FOUNDRY LTD		230986608	manufacture(84313-001)

Revised: 5/2024

TINA DAVIES PROFESSIONAL LLC