

SIMPLE PROMISE SIMPLE H HEMORRHOID RELIEF CREAM- phenylephrine hydrochloride, pramoxine hydrochloride cream
SIMPLE PROMISE PTE LTD

SIMPLE PROMISE Simple H Hemorrhoid Relief Cream

Drug Facts

Active ingredients

Phenylephrine HCl 0.25%

Pramoxine HCl 1%

Purpose

Vasoconstrictor

Local anesthetic

Uses

• for temporary relief of pain, soreness and burning • helps relieve the local itching and discomfort associated with hemorrhoids • temporarily shrinks hemorrhoid tissue • temporarily provides a coating for relief of anorectal discomforts • temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful

Warnings

For external use only

Do not use

this product if you have

• heart disease • high blood pressure • thyroid disease • diabetes • 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.
- attach the applicator to the tube. Lubricate the applicator well, then gently insert the

applicator into the rectum. **FOR INTRARECTAL USE:**

In case of bleeding, consult a doctor promptly.

Stop use and ask a doctor if

• condition worsens or does not improve within 7 days • an allergic reaction develops • the symptoms being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

• : when practical, cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with a tissue or a soft cloth before applying cream. • when first opening the tube, puncture foil seal with top end of cap • apply externally or in the lower portion of the anal canal only • apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement Children under 12 years of age: ask a doctor. **Adults**

Other information

• store at 20-25°C (68-77°F) • do not use if printed safety seal on cap is broken or missing

Inactive ingredients

Aqua (Deionized Water), Aloe Barbadensis Leaf (Aloe Vera Gel) Juice, Behentrimonium Methosulfate, Butyrospermum Parkii (Shea) Butter, Calendula Officinalis Extract, Caprylyl Glycol, Carbomer, Cetearyl Alcohol, Cetyl Alcohol, Cucumis Sativus (Cucumber) Extract, Decyl Glucoside, Dimethicone, Glycerin, Glyceryl Laurate, Glyceryl Stearate, Glyceryl Undecylenate, Glycyrrhiza Glabra (Licorice) Extract, Hamamelis Virginiana (Witch Hazel), Isopropyl Myristate, PEG-100 Stearate, Petrolatum, Polysorbate-20, Sodium Hydroxide, Stearic Acid, Stearyl Alcohol, Tetrasodium EDTA, Tocopheryl Acetate (Vitamin E), Xanthan Gum, Zemea (Corn) Propanediol.

Package Labeling: SIMPLE PROMISE Simple H Hemorrhoid Relief Cream, 2oz/56.7g

Distributed By:
Simple Promise Pte Ltd
3242 NE 3rd Avenue #1051,
Camas, WA 98607

Questions? Call us at
1-800-259-9522

To reorder, visit
<https://getsimpleh.com/reorder/>

SIMPLE H™

Hemorrhoid Relief Cream
With Calendula and Vitamin E

For the Temporary Relief of Pain, Itching, and Discomfort
Temporarily Reduces Swelling Associated With Irritated
Hemorrhoidal Tissue and Other Anorectal Disorders
Paraben-Free

1 TUBE
NET WT. 2 Oz (56.7 g)



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Warnings

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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

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- **FOR INTRARECTAL USE:** attach the applicator to the tube. Lubricate the applicator well, then gently insert the applicator into the rectum.

In case of bleeding, consult a doctor promptly.

Stop use and ask a doctor if

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- an allergic reaction develops
- the symptoms being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase.

Drug Facts (Continued)

If pregnant or breast-feeding, ask a health professional before use.
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 by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with a tissue or a soft cloth before applying cream.
 - when first opening the tube, puncture foil seal with top end of cap
 - apply externally or in the lower portion of the anal canal only
 - apply externally to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- Children under 12 years of age:** ask a doctor.

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SIMPLE PROMISE SIMPLE H HEMORRHOID RELIEF CREAM

phenylephrine hydrochloride, pramoxine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83311-335
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1W5297W6MV)	PHENYLEPHRINE	2.5 mg in 1 g
PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056)	PRAMOXINE HYDROCHLORIDE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BEHENTRIMONIUM METHOSULFATE (UNII: 5SHP745C61)	
SHEA BUTTER (UNII: K49155WL9Y)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CUCUMBER (UNII: YY7C30VXJT)	
DECYL GLUCOSIDE (UNII: Z17H97EA6Y)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL LAURATE (UNII: Y98611C087)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
HAMAMELIS VIRGINIANA ROOT BARK/STEM BARK (UNII: T7S323PKJS)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
EDETATE SODIUM (UNII: MP1J8420LU)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CORN (UNII: 0N8672707O)	
PROPANEDIOL (UNII: 5965N8W85T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83311-335-00	1 in 1 BOX	03/06/2023	
1		56.7 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	03/06/2023	

Labeler - SIMPLE PROMISE PTE LTD (659554958)

