

THERA PLUS HEMORRHOIDAL- glycerin, petrolatum, phenylephrine hydrochloride, pramoxine hydrochloride cream
FOURSTAR GROUP USA, INC.

Thera Plus Hemorrhoidal Cream

Drug Facts

Active ingredients

Glycerol 14.4%
Petrolatum 15%
Phenylephrine hydrochloride 0.25%
Pramoxine hydrochloride 1%

Purpose

Protectant
Vasoconstrictor
Local anesthetic

Uses

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

Warnings

For external use only.

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- urinating due to an enlarged prostate gland

When using this product

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

Stop use and ask a doctor if

- bleeding occurs
- condition worsens or does not improve within 7 days
- the symptoms being treated do not subside or if redness, irritation, swelling, pain or other symptoms develop or increase. some people can develop allergic reactions to ingredients in this product.

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 (1-800-222-1222).

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, especially at night or in the morning or after each bowel movement.
- apply externally or in the lower portion of the anal canal only.
- for application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into the anus.
- Children under 12 years of age: consult a doctor.

Other information

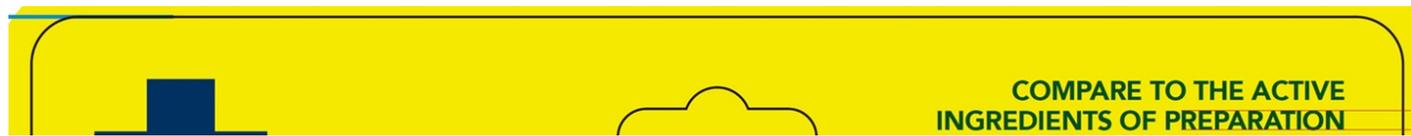
- store at room temperature 68 °- 77° F (20° - 25° C).

Inactive ingredients

aloe barbadensis leaf juice, carboxymethylcellulose sodium, cetyl alcohol, mono-and di-glycerides, methylparaben, mineral oil, propylene glycol, propylparaben , purified water, stearic acid,tween 80, xanthan gum

Questions?

1-800-639-3803Weekdays 9 AM to 4 PM EST

Package Labeling:

**COMPARE TO THE ACTIVE
INGREDIENTS OF PREPARATION**

Helps provide temporary relief from hemorrhoid itching, burning, and discomfort



Formula with Aloe

Hemorrhoidal Cream



Formula with Aloe

Includes Applicator Tip

NET WT. 0.9 OZ (26g)

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MANUFACTURED FOR:
FOURSTAR GROUP USA, INC.
925 GRANT ST., AKRON, OH 44311 USA
MADE IN CHINA

\$1.25



Drug Facts

Active ingredients

Glycerol 14.4% Protectant
Petrolatum 15% Protectant
Phenylephrine hydrochloride 0.25% Vasoconstrictor
Pramoxine hydrochloride 1% Local anesthetic

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Ask a doctor before use if you have

■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ urinating due to an enlarged prostate gland

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Stop use and ask a doctor if

■ bleeding occurs
■ condition worsens or does not improve within 7 days
■ the symptoms being treated do not subside or if redness, irritation,

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 (1-800-222-1222).

Directions Adults:

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■ store at room temperature 68° - 77° F (20° - 25° C).

Inactive ingredients aloe barbadensis leaf juice, carboxymethylcellulose sodium, cetyl alcohol, mono- and di-glycerides, methylparaben, mineral oil, propylene glycol, propylparaben, purified water, stearic acid, tween 80, xanthan gum

swelling, pain or other symptoms develop or increase. some people can develop allergic reactions to ingredients in this product.

Questions? 1-800-639-3803 Weekdays 9 AM to 4 PM EST



COMPARE TO THE ACTIVE INGREDIENTS OF PREPARATION H® CREAM*

Hemorrhoidal Cream

Helps provide temporary relief from hemorrhoid itching, burning, and discomfort



Formula with Aloe

Includes Applicator Tip

NET WT. 0.9 OZ (26g)

TAMPER-EVIDENT: Do not use if foil seal is broken or missing

Active ingredients Glycerol 14.4%, Petrolatum 15%, Phenylephrine hydrochloride 0.25%, Pramoxine hydrochloride 1% **Purpose** Protectant, Protectant, Vasoconstrictor, Local anesthetic **Uses** ■ for temporary relief of pain, soreness and burning ■ helps relieve the local itching and discomfort associated with hemorrhoids ■ temporarily provides a coating for relief of anorectal discomforts ■ temporarily protects the irritated anorectal surface to help make bowel movements less painful ■ temporarily shrinks hemorrhoidal tissue **Warnings** For external use only. Ask a doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland **When using this product** ■ do not put this product into the rectum by using fingers or any mechanical device or applicator ■ do not exceed recommended daily dosage unless directed by a doctor **Stop use and ask a doctor if** ■ bleeding occurs ■ condition worsens or does not improve within 7 days ■ the symptoms being treated do not subside or if redness, irritation, swelling, pain or other symptoms develop or increase. some people can develop allergic reactions to ingredients in this product. 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 (1-800-222-1222). **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, especially at night or in the morning or after each bowel movement. ■ apply externally or in the lower portion of the anal canal only. ■ for application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate dispensing cap well, then gently insert dispensing cap partway into the anus. ■ Children under 12 years of age: consult a doctor. **Other information** ■ store at room temperature 68° - 77° F (20° - 25° C). **Inactive ingredients** aloe barbadensis leaf juice, carboxymethylcellulose sodium, cetyl alcohol, mono- and di-glycerides, methylparaben, mineral oil, propylene glycol, propylparaben, purified water, stearic acid, tween 80, xanthan gum

Questions? 1-800-639-3803 Weekdays 9 AM to 4 PM EST

MANUFACTURED FOR: FOURSTAR GROUP USA, INC.
925 GRANT ST., AKRON, OH 44311 USA
MADE IN CHINA LOT: EXP:

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THERA PLUS HEMORRHOIDAL

glycerin, petrolatum, phenylephrine hydrochloride, pramoxine hydrochloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80684-141
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	144 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	150 mg in 1 g
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)

CETYL ALCOHOL (UNII: 936JST6JCN)

METHYLPARABEN (UNII: A2I8C7HI9T)

MINERAL OIL (UNII: T5L8T28FGP)

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)

PROPYLPARABEN (UNII: Z8IX2SC1OH)

WATER (UNII: 059QF0KO0R)

STEARIC ACID (UNII: 4ELV7Z65AP)

POLYSORBATE 80 (UNII: 6OZP39ZG8H)

XANTHAN GUM (UNII: TTV12P4NEE)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80684-141-00	26 g in 1 TUBE; Type 0: Not a Combination Product	03/03/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	03/03/2025	

Labeler - FOURSTAR GROUP USA, INC. (140099503)

Revised: 3/2025

FOURSTAR GROUP USA, INC.