

GLYCERIN, PHENYLEPHRINE HYDROCHLORIDE, PRAMOXINE, WHITE PETROLATUM - glycerin, phenylephrine hydrochloride, pramoxine, white petrolatum cream
Target Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DRUG FACTS

ACTIVE INGREDIENTS

Glycerin, USP 14.4%

Phenylephrine HCl, 0.25%

Pramoxine HCl, 1%

White petrolatum, 15%

PURPOSE

Protectant

Vasoconstrictor

Local anesthetic

Protectant

USES

- Temporarily relieves pain, soreness and burning
- Helps relieve the local itching and discomfort associated with hemorrhoids
- Temporarily shrinks hemorrhoidal 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

Ask a doctor before use if you have

- heart disease
- thyroid disease
- high blood pressure
- diabetes
- 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

Stop use and ask a doctor if

- bleeding occurs
- the introduction of the applicator causes additional pain
- condition worsens or does not improve within 7 days
- an allergic reaction develops
- the symptom being treated does not subside or if redness, irritation, swelling, pain or other symptoms develop or increase

If pregnant or breastfeeding

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 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
- For application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate applicator well, then gently insert applicator into the rectum.
- Thoroughly clean dispensing cap after each use and replace cover

Children under 12 years: ask a doctor.

OTHER INFORMATION

Store at room temperature: 20° - 25° C (68° - 77° F)

INACTIVE INGREDIENTS

aloe barbadensis leaf extract, BHA, carboxymethylcellulose sodium, cetyl alcohol, citric acid, edetate disodium, glyceryl stearate, laureth-23, methylparaben, mineral oil, panthenol, propyl gallate, propylene glycol, propylparaben, purified water, sodium benzoate, steareth-2, steareth-20, stearyl alcohol, tocopherol. vitamin E, xanthan gum

Questions?

Call 1-800-910-6874

PACKAGE INFORMATION - TUBE

up and up

NDC 11673-572-24

Hemorrhoidal Cream

maximum strength

Compare to Preparation H® Hemorrhoidal Cream*

Helps shrink swelling of irritated hemorrhoidal tissues

NET WT 1.8 OZ (51 g)

This tube is sealed and packaged in a carton. Do not buy if carton is missing . Do not use if the seal under the cap has been punctured or if the tube is damaged.

*This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark Preparation H®.

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Minneapolis, MN 55403
Made in U.S.A.

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| Drug Facts | Drug Facts (cont'd) | Drug Facts (cont'd) | Drug Facts (cont'd) <small>Rev. A0409</small> |
|---|---|--|--|
| Active ingredient Purpose Glycerin, USP 14.4%Protectant Phenylephrine HCl, 0.25%Vasoconstrictor Pramoxine HCl, 1% Local anesthetic White petrolatum, 15%Protectant | Warnings Ask a doctor before use if you have ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ 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. Stop use and ask a doctor if ■ bleeding occurs ■ the introduction of the applicator into the rectum causes additional pain ■ condition worsens or does not improve within 7 days ■ an allergic reaction develops. 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 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. ■ For application in the lower anal canal: remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate applicator well, then gently insert applicator into the rectum. ■ Thoroughly clean dispensing cap after each use and replace cover Children under 12 years: ask a doctor. | Other information Store at room temperature: 20° – 25° C (68° – 77° F) Inactive ingredients aloe barbadensis leaf extract, BHA, carboxymethylcellulose sodium, cetyl alcohol, citric acid, edetate disodium, glyceryl stearate, laureth-23, methylparaben, mineral oil, panthenol, propyl gallate, propylene glycol, propylparaben, purified water, sodium benzoate, steareth-2, steareth-20, stearyl alcohol, tocopherol, vitamin E, xanthan gum Questions? Call 1-800-910-6874 245 05 0111 ID079479 Dist. by Target Corp. Minneapolis, MN 55403 Made in U.S.A. © & © 2009 Target Brands, Inc. All Rights Reserved Shop Target.com |

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NDC 11673-572-24



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hemorrhoidal cream
maximum strength

Compare to Preparation H® Hemorrhoidal Cream*

helps shrink swelling of irritated hemorrhoidal tissues

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NO COPY

PACKAGE INFORMATION - BOX

up and up

NDC 11673-572-24

Hemorrhoidal Cream maximum strength

Compare to Preparation H® Hemorrhoidal Cream*

Helps shrink swelling of irritated hemorrhoidal tissues



NET WT 1.8 OZ (51 g)

DO NOT USE IF SEAL UNDER CAP OF TUBE IS BROKEN OR MISSING WHEN PURCHASED.

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|---|--|--|
| <p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ The symptom 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. <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <p>Adults:</p> <ul style="list-style-type: none"> ■ 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. | <p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ 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. ■ For application in the lower anal canal, remove cover from dispensing cap. Attach dispensing cap to tube. Lubricate applicator well, then gently insert applicator into the rectum. ■ Thoroughly clean dispensing cap after each use and replace cover. <p>Children under 12 years: ask a doctor.</p> <p>Other information</p> <p>Store at room temperature: 20° – 25° C (68° – 77° F)</p> | <p>Drug Facts (continued)</p> <p>Inactive ingredients: aloe barbadensis leaf extract, BHA, Carbocymethylocellulose sodium, cetyl alcohol, citric acid, edetate disodium, glyceryl stearate, laureth-23, methylparaben, mineral oil, panthenol, propyl gallate, propylene glycol, propylparaben, purified water, sodium benzoate, stearic acid, steareth-20, stearyl alcohol, tocopherol, vitamin E, xanthan gum</p> <p>Questions? Call 1-800-910-6874</p> |
| <p>DO NOT USE IF SEAL UNDER CAP OF TUBE IS BROKEN OR MISSING WHEN PURCHASED.</p> <p>This product is not manufactured or distributed by Wyeth Consumer Healthcare, owner of the registered trademark Preparation H®.</p> <p>245 05 0111 ID079479 Distributed by Target Corporation Minneapolis, MN 55403 Made in U.S.A. © & © 2009 Target Brands, Inc. All Rights Reserved Shop Target.com</p> <p>UPC-A FPO 3 50730 00607 1</p> | | |
| <p>NDC 11673-572-24</p> <p>up&up  </p> <p>hemorrhoidal cream maximum strength</p> <p>Compare to Preparation H® Hemorrhoidal Cream* helps shrink swelling of irritated hemorrhoidal tissues</p> <p>NET WT 1.8 OZ (51 g)</p> | | |
| <p>Drug Facts</p> <p>Active ingredient</p> <p>Glycerin, USP 14.4% ————— Protectorant Phenylephrine HCl, 0.25% ————— Vasoconstrictor Pramoxine HCl, 1% ————— Local anesthetic White petrolatum, 15% ————— Protectorant</p> <p>Purpose</p> <p>Temporarily relieves pain, soreness and burning Helps relieve the local itching and discomfort associated with hemorrhoids</p> | <p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ Temporarily shrinks hemorrhoidal tissue ■ Temporarily provides a coating for relief of anorectal discomforts ■ Temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful <p>Warnings</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ heart disease ■ thyroid disease ■ high blood pressure ■ diabetes ■ difficulty in urination due to enlargement of the prostate gland | <p>Drug Facts (continued)</p> <p>Ask a doctor or pharmacist before use if you are presently taking a prescription drug for high blood pressure or depression.</p> <p>When using this product do not exceed the recommended daily dosage unless directed by a doctor</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ bleeding occurs ■ the introduction of the applicator into the rectum causes additional pain ■ condition worsens or does not improve within 7 days ■ an allergic reaction develops |

33-4012TAC
Rev. A0409

GLYCERIN, PHENYLEPHRINE HYDROCHLORIDE, PRAMOXINE, WHITE PETROLATUM

glycerin, phenylephrine hydrochloride, pramoxine, white petrolatum cream

Product Information

| | | | |
|-------------------------|-----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:11673-572 |
| Route of Administration | RECTAL, TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-----------------------------|------------------|
| GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX) | GLYCERIN | 0.144 mg in 1 g |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 0.0025 mg in 1 g |
| PRAMOXINE HYDROCHLORIDE (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056) | PRAMOXINE HYDROCHLORIDE | 0.01 mg in 1 g |
| PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U) | PETROLATUM | 0.15 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U) | |
| CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| LAURETH-23 (UNII: N72LMW566G) | |
| METHYL PARABEN (UNII: A2I8C7H9T) | |
| LIGHT MINERAL OIL (UNII: N6K5787QVP) | |
| PANTHENOL (UNII: WV9CM0067Z) | |
| PROPYL GALLATE (UNII: 8D4SNN7V92) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0K00R) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| ALPHA-TOCOPHEROL (UNII: H4N855PNZ1) | |
| .ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------------------|----------------------|--------------------|
| 1 | NDC:11673-572-24 | 1 in 1 BOX | | |
| 1 | | 51 g in 1 TUBE, WITH APPLICATOR | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part346 | 04/01/2009 | |

Labeler - Target Corporation (006961700)

Revised: 2/2010

Target Corporation