

PREPARATION H- mineral oil, petrolatum, phenylephrine hcl ointment
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Drug Facts

ACTIVE INGREDIENTS

Mineral oil 14%

Petrolatum 74.9%

Phenylephrine HCl 0.25%

PURPOSES

Protectant

Protectant

Vasoconstrictor

USES

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue and relieves burning
- 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 and/or intrarectal use only

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

- condition worsens or does not improve within 7 days
- introduction of applicator into the rectum causes additional pain

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 ointment.
- when first opening the tube, puncture foil seal with top end of cap
- apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement
- intrarectal use:
 - remove cover from applicator, attach applicator to tube, lubricate applicator well and gently insert applicator into the rectum
 - thoroughly cleanse applicator after each use and replace cover
- also apply ointment to external area
- regular use provides continual therapy for relief of symptoms
- children under 12 years of age: ask a doctor

OTHER INFORMATION

store at 20-25°C (68-77°F)

INACTIVE INGREDIENTS

benzoic acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, thymus vulgaris (thyme) flower/leaf oil, tocopherols excipient, white wax

QUESTIONS OR COMMENTS?

Call weekdays 9 AM to 5 PM EST at **1-800-99PrepH** or **1-800-997-7374**.

PRINCIPAL DISPLAY PANEL - 28 g Tube Label

THIS PACKAGE CONTAINS AN OUTER CARTON. DO NOT BUY IF OUTER CARTON IS MISSING.


PREPARATION H[®]
HEMORRHOIDAL OINTMENT

Prevents Further

Irritation

- Prompt, Soothing Relief from Painful Burning, Itching and Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal and External Discomfort

NET WT 1 OZ (28 g)

THIS PACKAGE CONTAINS AN OUTER CARTON. DO NOT BUY IF OUTER CARTON IS MISSING.	
 PREPARATION H[®] HEMORRHOIDAL OINTMENT	Prevents Further Irritation <ul style="list-style-type: none">• Prompt, Soothing Relief from Painful Burning, Itching and Discomfort• Shrinks Swollen Hemorrhoidal Tissue• Protects Irritated Tissue• Relieves Internal and External Discomfort NET WT 1 OZ (28 g)
<p>Active ingredients Mineral oil 14%, Petrolatum 74.9%, Phenylephrine HCl 0.25%</p> <p>Uses helps relieve the local itching and discomfort associated with hemorrhoids; temporarily shrinks hemorrhoidal tissue and relieves burning; temporarily provides a coating for relief of anorectal discomforts; temporarily protects the inflamed, irritated anorectal surface to help make bowel movements less painful.</p> <p>Warnings For external and/or intrarectal use only 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; condition worsens or does not improve within 7 days; introduction of applicator into the rectum causes additional pain. 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.</p>	<p>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 ointment; when first opening the tube, puncture foil seal with top end of cap; apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement. Intrarectal use: remove cover from applicator, attach applicator to tube, lubricate applicator well and gently insert applicator into the rectum, thoroughly cleanse applicator after each use and replace cover; also apply ointment to external area; regular use provides continual therapy for relief of symptoms. Children under 12 years of age: ask a doctor.</p> <p>Other information store at 20-25°C (68-77°F)</p> <p>Inactive ingredients benzoic acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, thymus vulgaris (thyme) flower/leaf oil, tocopherols excipient, white wax</p> <p style="border: 1px solid black; padding: 2px; display: inline-block;">Do Not Use if tube seal under cap embossed with "H" is broken or missing.</p> <p>For most recent product information, visit www.preparationh.com Marketed by: Pfizer, Madison, NJ 07940 USA © 2016 Pfizer Inc. PAA071388</p>

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

PREPARATION H[®] HEMORRHOIDAL OINTMENT

Prevents Further Irritation

- Prompt, Soothing Relief from Painful Burning, Itching and Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal and External Discomfort

NET WT 1 OZ (28 g)



PRINCIPAL DISPLAY PANEL - 28 g Tube Label - PAA119867

PREPARATION H[®]

HEMORRHOIDAL
 OINTMENT

Prevents Further
 Irritation

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal & External Discomfort

NET WT 1.0 OZ (28 g)



PRINCIPAL DISPLAY PANEL - 28 g Tube Carton - PAA119868

PREPARATION H®

HEMORRHOIDAL
 OINTMENT

Prevents Further
 Irritation

New Look,
 SAME SIZE!

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal & External Discomfort

1 TUBE | NET WT 1 OZ (28 g)

PREPARATION H®

HEMORRHOIDAL OINTMENT

Prevents Further Irritation

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal & External Discomfort

1 TUBE | NET WT 1 OZ (28 g)

New Look, SAME SIZE!

Drug Facts (continued)

- Intraanal use.
- Remove cover from applicator, attach applicator to tube, insert applicator well and gently insert applicator into the rectum.
- Thoroughly clean applicator after each use and replace cover.
- Also apply ointment to external area.
- If your use provides continued therapy for relief of symptoms.
- Children under 12 years of age: ask a doctor.

Drug Facts (continued)

Other information see at 20-25°C (68-77°F)

Inactive ingredients baroc acid, butylated hydroxytoluene, cam oil, glycerin, lanolin alcohol, methylparaben, mineral oil, paraffin, propylparaben, purified water, thymus virginicus (thyme) flower oil, tocopherols excepted, white wax.

Questions or comments? Call weekdays 9 AM to 5 PM EST at 1-800-99PrepH or 1-800-997-7374

For most recent product information, visit www.preparationh.com.
Marketed by: Pfizer, Madison, NJ 07940 USA
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Made in Canada

Do Not Use If Tube Seal is Broken or Missing.

81% For Position Only

3 0573 2871 93 6

PREPARATION H®

HEMORRHOIDAL OINTMENT

Prevents Further Irritation

1 TUBE | NET WT 1 OZ (28 g)

New Look, SAME SIZE!

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal & External Discomfort

Drug Facts (continued)

- Stop use and ask a doctor if
- bleeding occurs
 - condition worsens or does not improve within 7 days
 - introduction of applicator into the rectum causes additional pain

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

Drug Facts (continued)

- 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.

Drug Facts (continued)

- temporarily provides a coating for relief of anal discomforts
- temporarily protects the inflamed, irritated anal surface to help make bowel movements less painful

Warnings

For external and/or intraanal use only.
Ask a doctor before use if you have

- heart disease
- high blood pressure

Drug Facts

Active ingredients Purposes

Mineral oil 14%..... Protectant
Petrolatum 74.9%..... Protectant
Phenylephrine HCl 0.25%..... Vasoconstrictor

Uses

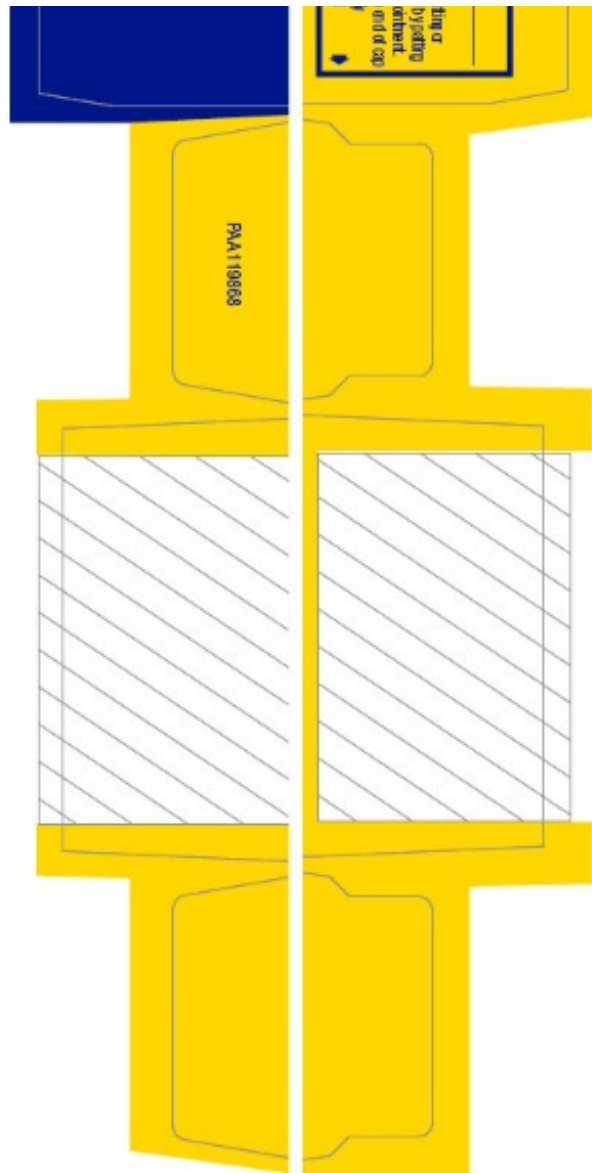
- helps relieve the local itching and discomfort associated with hemorrhoids
- temporarily shrinks hemorrhoidal tissue and relieves burning

Drug Facts (continued)

Directions

As able, when practical, cleanse the affected area by bathing with appropriate cleansing wipe. Gently dry or dabbing with tissue or a soft cloth before applying. Wash hands thoroughly with soap and water. Apply a thin layer of ointment to the affected area up to 4 times daily, especially at night, at the morning or after and toward movement.





PRINCIPAL DISPLAY PANEL - 57 g Tube Label

PREPARATION H[®]

HEMORRHOIDAL
OINTMENT

Prevents Further
Irritation

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
- Protects Irritated Tissue
- Relieves Internal & External Discomfort

NET WT 2.0 OZ (57 g)

<p>Questions or comments? Call weekdays 9 AM to 5 PM EST at 1-800-99PrepH or 1-800-997-7374</p>	<p>THIS PACKAGE CONTAINS AN OUTER CARTON. DO NOT BUY IF OUTER CARTON IS MISSING.</p>
<p>For most recent product information, visit www.preparationh.com Marketed by: Pfizer, Madison, NJ 07940 USA © 2020 Pfizer Inc.</p>	<p>Do Not Use If tube seal under cap embossed with "H" is broken or missing.</p>
<p>PREPARATION H[®]</p>	<p>HEMORRHOIDAL OINTMENT Prevents Further Irritation</p> <ul style="list-style-type: none"> • Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort • Shrinks Swollen Hemorrhoidal Tissue • Protects Irritated Tissue • Relieves Internal & External Discomfort
<p>NET WT 2.0 OZ (57 g)</p>	
<p>Active Ingredients Mineral oil 14%, Petrolatum 74.9%, Phenylephrine HCl 0.25% Uses helps relieve the local itching and discomfort associated with hemorrhoids; temporarily shrinks hemorrhoidal tissue and relieves burning; 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 and/or intrarectal use only 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; condition worsens or does not improve within 7 days; introduction of applicator into the rectum causes additional pain.</p>	<p>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 ointment; when first opening the tube, puncture foil seal with top end of cap; apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement. Intrarectal use: remove cover from applicator, attach applicator to tube, lubricate applicator well and gently insert applicator into the rectum, thoroughly cleanse applicator after each use and replace cover; also apply ointment to external area; regular use provides continual therapy for relief of symptoms. Children under 12 years of age: ask a doctor. Other information store at 20-25°C (68-77°F) Inactive Ingredients benzoic acid, butylated hydroxyanisole, corn oil, glycerin, lanolin, lanolin alcohols, methylparaben, mineral oil, paraffin, propylparaben, purified water, thymus vulgaris (thyme) flower/leaf oil, tocopherols excipient, white wax</p>  <p>PAA136097</p>

PRINCIPAL DISPLAY PANEL - 57g Tube Carton

PREPARATION H[®]

HEMORRHOIDAL
OINTMENT

Prevents Further
Irritation

- Prompt, Soothing Relief from Painful Burning, Itching, & Discomfort
- Shrinks Swollen Hemorrhoidal Tissue
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- Relieves Internal & External Discomfort

1 TUBE | NET WT 2 OZ (57 g)

PREPARATION H[®]

HEMORRHOIDAL OINTMENT

Prevents Further Irritation

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 1 TUBE | NET WT 2 OZ (57 g)

81% For Position Only
3 0573 2871 94 3

Do Not Use if Tube seal under cap embossed with "H" is broken or missing.
For more recent product information, visit www.pfizer.com/hem.
Marketed by Pfizer Inc., New York, NY 07090 USA
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Made in Canada

Drug Facts (continued)

Interact:

- remove cap from applicator, attach applicator to tube
- lubricate applicator well and gently insert applicator into the rectum
- thoroughly cleanse applicator after each use and replace cover
- also apply ointment to external area
- require use provides continued therapy for relief of symptoms
- children under 12 years of age, ask a doctor

Other Information (Rev. 01/20/20) C (08-77-9)

Drug Facts (continued)

Inactive ingredients

benzoic acid, butylated hydroxytoluene, camphor, glycerin, benzoin alcohol, methylparaben, mineral oil, paraffin, polypropylene, purified water, thymol, and waxes (thymol).
Questions or comments?
Call weekdays 9 AM to 5 PM EST at 1-800-999-7374 or 1-800-999-7374

PREPARATION H[®]

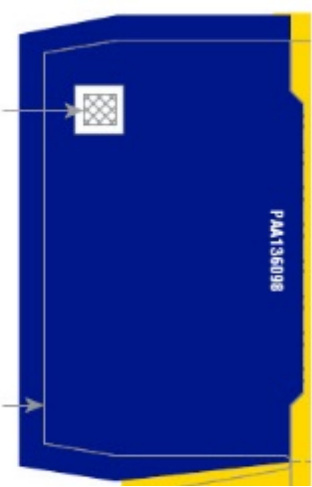
HEMORRHOIDAL OINTMENT

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 1 TUBE | NET WT 2 OZ (57 g)

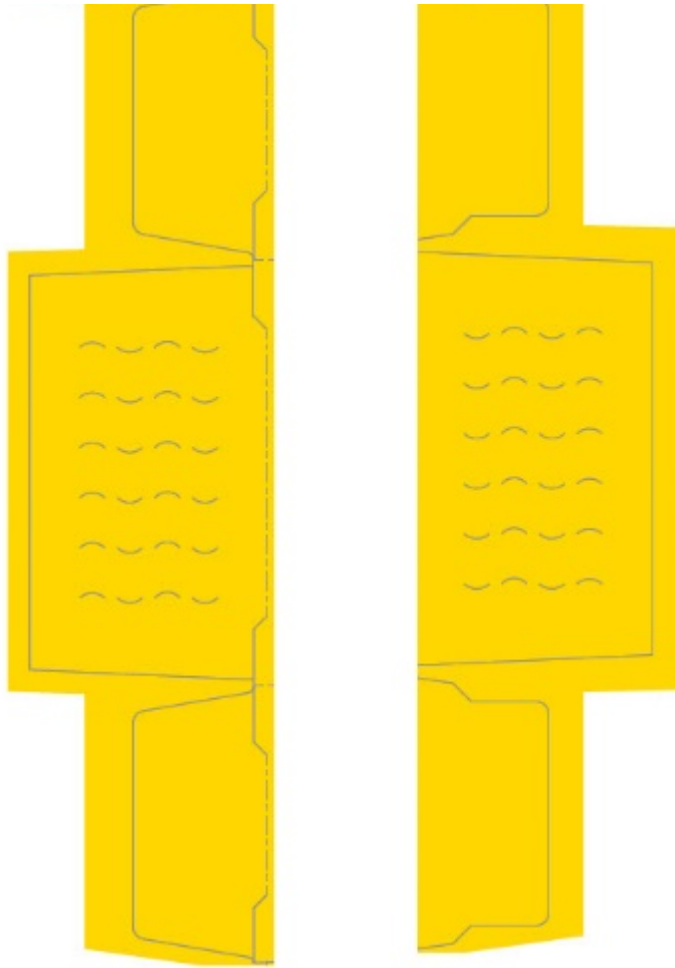
<p>Drug Facts</p> <p>Active ingredients</p> <p>Mineral oil 14% Protectant Petrolatum 74.9% Protectant Phenylephrine HCl 0.25% Vasoconstrictor</p> <p>Purposes</p> <p>Mineral oil 14% Protectant Petrolatum 74.9% Protectant Phenylephrine HCl 0.25% Vasoconstrictor</p> <p>Uses</p> <ul style="list-style-type: none"> ■ helps relieve the local itching and discomfort associated with hemorrhoids ■ temporarily shrinks hemorrhoidal tissue and relieves burning 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ 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>For external and/or intrarectal use only</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> ■ heart disease ■ high blood pressure 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ■ thyroid disease ■ diabetes ■ difficulty in urination due to enlargement of the prostate gland <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>Drug Facts (continued)</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ bleeding occurs ■ condition worsens or does not improve within 7 days ■ introduction of applicator into the rectum causes additional pain <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>
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Drug Facts (continued)

Directions

- adults: when punctured, 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 ointment.
- when first opening the tube, puncture foil seal with top end of cap
- apply to the affected area up to 4 times daily, especially at night, in the morning or after each bowel movement



PREPARATION H

mineral oil, petrolatum, phenylephrine hcl ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-2871
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 1 g
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	140 mg in 1 g
PETROLATUM (UNII: 4T6H12BN9U) (PETROLATUM - UNII:4T6H12BN9U)	PETROLATUM	749 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BENZOIC ACID (UNII: 8SKN0B0MIM)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	

CORN OIL (UNII: 8470G57WFM)
GLYCERIN (UNII: PDC6A3C0OX)
LANOLIN (UNII: 7EV65EAW6H)
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)
METHYLPARABEN (UNII: A2I8C7HI9T)
PARAFFIN (UNII: I9O0E3H2ZE)
PROPYLPARABEN (UNII: Z8IX2SC1OH)
WATER (UNII: 059QF0KO0R)
THYME (UNII: CW657OBU4N)
WHITE WAX (UNII: 7G1J5DA97F)
TOCOPHEROL (UNII: R0ZB2556P8)

Product Characteristics

Color	yellow (smooth yellow ointment)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-2871-10	1 in 1 CARTON	03/01/2004	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:0573-2871-20	1 in 1 CARTON	03/01/2004	
2		57 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:0573-2871-04	2 in 1 PACKAGE	03/01/2004	
3		1 in 1 CARTON		
3		57 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:0573-2871-91	1 in 1 CARTON	03/01/2018	
4		28 g in 1 TUBE; Type 0: Not a Combination Product		
5	NDC:0573-2871-92	1 in 1 CARTON	03/01/2018	
5		57 g in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:0573-2871-93	1 in 1 CARTON	06/01/2019	
6		28 g in 1 TUBE; Type 0: Not a Combination Product		
7	NDC:0573-2871-94	1 in 1 CARTON	05/17/2020	
7		57 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	03/01/2004	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Establishment

Name	Address	ID/FEI	Business Operations
Pf Soins De Santé Sri		203812479	analysis(0573-2871) , label(0573-2871) , manufacture(0573-2871) , pack(0573-2871)

Revised: 11/2023

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC