ENVIO 90 DAY DAILY ESSENTIALS DUO SUB SHIPMENT- benzoyl peroxide and salicylic acid Smart Skin Health, LLC

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.

ENVIO™ 90 Day Daily Essentials Duo Sub Shipment B.P.O. CLEANSER

Drug Facts

Active Ingredients

Benzoyl Peroxide 5%

Purpose

Acne Treatment Gel

Use

for the management of acne

Warnings

For external use only

When using this product

- skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time
- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with the eyes, lips, and mouth
- avoid contact with hair and dyed fabrics, which may be bleached by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling, or
 possibly swelling. Irritation may be reduced by using the product less frequently or in
 a lower concentration.

Do not use if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

Stop use and ask a doctor

if irritation becomes severe

Keep out of reach of children

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

Directions

- apply a small amount to dampened skin
- cover the entire affected area with a thin layer and rinse thoroughly one to three times daily
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day
- if going outside, apply sunscreen after using this product
- if irritation or sensitivity develops, stop use of both products and ask a doctor. Sensitivity Test for a New User: Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.

Inactive Ingredients

Water, Sodium C14-16 Olefin Sulfonate, Glycerin, Acrylates Copolymer, Cocamidopropyl Betaine, Cetearyl Alcohol, Glycol Distearate, Cetyl Alcohol, Panthenol, Aloe Barbadensis Leaf Extract, Sodium Hyaluronate, Allantoin, Ethylhexylglycerin, Phenoxyethanol, Sodium Hydroxide

Other Information

Protect this product from excessive heat and direct sun.

Questions or Comments

Toll Free within USA 833-93-ENVIO

Dist. By: Smart Skin Health, LLC, Naples, FL 34108

S.A. Serum

Drug Facts

Active Ingredients

Salicylic Acid 2%

Purpose

Acne Gel Treatment

Use

Warnings

For external use only

When using this product

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- avoid unnecessary sun exposure and use a sunscreen
- avoid contact with the eyes, lips, and mouth
- avoid contact with hair and dyed fabrics, which may be bleached by this product
- skin irritation may occur, characterized by redness, burning, itching, peeling, or
 possibly swelling. Irritation may be reduced by using the product less frequently or in
 a lower concentration.

Do not use if you

- have very sensitive skin
- are sensitive to Salicylic Acid

Stop use and ask a doctor if irritation becomes severe

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

Directions

- apply evenly to affected area and allow to dry completely
- Can be used twice daily or as directed by a doctor
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day
- if irritation or sensitivity develops, stop use of both products and ask a doctor.
 Sensitivity Test for a New User: Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.

Inactive Ingredients

Water, Hydroxypropyl Starch Phosphate, Glycerin, Decyl Glucoside, Hamamelis Virginiana (Witch Hazel) Bark Extract, Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-6 Caprylate/Caprate, Melaleuca Alternafolia (Tea Tree) Leaf Oil, Allantoin, Panthenol, Xanthan Gum, Glyceryl Stearate, Glyceryl Stearate Citrate, Lavandula Hybrida (Lavender Grosso) Oil¹, Salix Alba (Willow) Bark Extract, Camellia Sinensis (Green Tea) Leaf Extract¹, Ethylhexylglycerin, Phenoxyethanol

Other Information

Protect this product from excessive heat and direct sun.

Questions?

Toll Free within USA 833-93-ENVIO

Dist. By: Smart Skin Health, LLC, Naples, FL 34108

PRINCIPAL DISPLAY PANEL - Kit Carton

envio



PRINCIPAL DISPLAY PANEL - 133 mL Tube Label

envio™ skin

B.P.O. 5% CLEANSER Benzoyl Peroxide Acne Treatment

4.5 fl. oz. / 133 mL

Envio's 5% B.P.O. Cleanser was developed to gently eliminate and prevent acne-causing bacteria without aggravating the skin. It is formulated with Aloe Vera and Allantoin to soothe and calm irritated skin; as well as Pro-Vitamin B5 (Panthenol), which attracts and retains moisture to help improve skin softness.

DERMATOLOGIST RECOMMENDED

Drug Facts Active Ingredients Purpose Benzoyl Peroxide 5% Acne Treatment Gel

Use for the management of acne

Warnings

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When using this product • skin initiation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time • avoid unnecessary sun exposure and use a sunscreen • avoid contact with the eyes, lips, and mouth • avoid contact with hair and dyed fabrics, which may be bleached by this product • skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

Do not use if you . have very sensitive skin . are sensitive to benzoyl peroxide

Stop use and ask a doctor . if irritation becomes severe

Keep out of reach of children • If swallowed, get medical help or contact a Poison Control Center right away.

Directions: • apply a small amount to dampened skin • cover the entire affected area with a thin layer and rinse thoroughly one to three times daily • because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor • if bothersome dryness or peeling occurs, reduce application to once a day or every other day • if going outside, apply sunscreen after using this product • if initiation or sensitivity develops, stop use of both products and ask a doctor. Sensitivity Test for a New User: Apply product spaningly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.

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Other Information: Protect this product from excessive heat and direct sun.

Questions or Comments: Toll Free within USA 833-93-ENVIO



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Dist. By: Smart Skin Health, LLC, Naples, FL 34108 Manufactured in the USA Free of Fragrance, Parabens, Sulfates, Phthalates

Please Recycle 🕸

EN.0102

B.P.O. 5% CLEANSER
Benzoyl Peroxide Acne Treatment
4.5 fl. oz./133 mL

PRINCIPAL DISPLAY PANEL - 48 g Tube Label

envio™ skin

S.A. 2% GEL SERUM Salicylic Acid Acne Treatment

1.7 oz /48 g

Drug Facts

Use for the management of acne

Warnings

For external use only

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Do not use if you • have very sensitive skin • are sensitive to Salicylic Acid

Stop use and ask a doctor if irritation becomes severe

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

Directions: • apply evenly to affected area and allow to dry completely • Can be used twice daily or as directed by a doctar • because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor • if bothersome dryness or peeling occurs, reduce application to once a day or every other day • if initiation or sensitivity develops, stop use of both products and ask a doctor. Sensitivity Test for a New User. Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfart occurs, follow the directions stated above.

Inactive Ingredients: Water, Hydroxypropyl Starch Phosphate, Glycerin, Decyl Glucoside, Hamamelis Virginiana (Witch Hazel) Bark Extract, Polyglyceryl-4 Laurate/Sebacate, Polyglyceryl-6 Caprylate/Caprate, Melaleuca Alternafolia (Tea Tree) Leaf Oil, Allantoin, Panthenol, Xanthan Gum, Glyceryl Stearate, Glyceryl Stearate Citrate, Lavandula Hybrida (Lavender Grosso) Oil*, Salix Alba (Willow) Bark Extract, Camellia Sinensis (Green Tea) Leaf Extract*, Ethylhexylglycerin, Phenoxyethanol

Other Information: Protect this product from excessive heat and direct sun.

Questions? Toll Free within USA 833-93-ENVIO

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Please Recycle





S.A. 2% GEL SERUM Salicylic Acid Acne Treatment 1.7 oz/48 g

ENVIO 90 DAY DAILY ESSENTIALS DUO SUB SHIPMENT

benzoyl peroxide and salicylic acid kit

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81252-2000

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# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:81252-2000-1	1 in 1 CARTON	10/21/2021	

Quantity of Parts				
Part #	Package Quantity	Total Product Quantity		
Part 1	1 TUBE	133 mL		
Part 2	1 TUBE	48 g		

Part 1 of 2

B.P.O. CLEANSER

benzoyl peroxide gel

Product Information

Item Code (Source) NDC:81252-0102

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Benzoyl Peroxide (UNII: W9WZ N9A0GM) (Benzoyl Peroxide - UNII: W9WZ N9A0GM)	Benzoyl Peroxide	5 g in 100 mL		

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Sodium C14-16 Olefin Sulfonate (UNII: O9W3D3YF5U)	
Glycerin (UNII: PDC6A3C0OX)	
Cocamidopropyl Betaine (UNII: 50CF3011KX)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Glycol Distearate (UNII: 13W7MDN21W)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Panthenol (UNII: WW9CM0067Z)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Hyaluronate Sodium (UNII: YSE9PPT4TH)	
Allantoin (UNII: 344S277G0Z)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Sodium Hydroxide (UNII: 55X04QC32I)	

F	Packaging			
#	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81252- 0102-1	133 mL 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 final	part333D	10/21/2021		

Part 2 of 2

S.A. SERUM

salicylic acid gel

Product Information

Item Code (Source) NDC:81252-0202

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)
Salicylic Acid 2 g in 100 g

Inactive Ingredients				
Ingredient Name	Strength			
Water (UNII: 059QF0KO0R)				
Glycerin (UNII: PDC6A3C0OX)				
Decyl Glucoside (UNII: Z17H97EA6Y)				
Witch Hazel (UNII: 101I4J0U34)				
Tea Tree Oil (UNII: VIF565UC2G)				
Allantoin (UNII: 344S277G0Z)				
Panthenol (UNII: W/9CM0O67Z)				
Xanthan Gum (UNII: TTV12P4NEE)				
Glyceryl Monostearate (UNII: 2300U9XXE4)				
Glyceryl Stearate Citrate (UNII: WH8T92A065)				
Ylang-Ylang Oil (UNII: 8YOY78GNNX)				
Salix Alba Bark (UNII: 205MXS71H7)				
Green Tea Leaf (UNII: W2ZU1RY8B0)				
Ethylhexylglycerin (UNII: 147D247K3P)				
Phenoxyethanol (UNII: HIE492ZZ3T)				

P	Packaging					
# Item Code Package Description		Marketing Start Date	Marketing End Date			
	NDC:81252-	48 g in 1 TUBE; Type 0: Not a Combination				

0202-1	Product		
Marketing I	nformation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	10/21/2021	
Marketing I	nformation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	10/21/2021	

Labeler - Smart Skin Health, LLC (117039871)

Revised: 1/2023 Smart Skin Health, LLC