

ENVIO 30 DAY DAILY ESSENTIALS DUO- 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™ 30 Day Daily Essentials Duo

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

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 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/Caprates, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Allantoin, Panthenol, Xanthan Gum, Glyceryl Stearate, Glyceryl Stearate Citrate, Lavandula Hybrid (Lavender Grosso) Oil¹, Salix Alba (Willow) Bark Extract, Camellia Sinensis (Green Tea) Leaf Extract¹, Ethylhexylglycerin, Phenoxyethanol

¹ Certified Organic Ingredients

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 - 44 mL Tube Label

envio™
skin

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

1.5 fl. oz. /44 mL

Drug Facts	
Active Ingredients	Purpose
Benzoyl Peroxide 5%.....	Acne Treatment Gel
Use for the management of acne	
Warnings For external use only.	
<p>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.</p>	
<p>Do not use if you • have very sensitive skin • are sensitive to benzoyl peroxide</p>	
<p>Stop use and ask a doctor • if irritation becomes severe</p>	
<p>Keep out of reach of children • If swallowed, get medical help or contact a Poison Control Center right away.</p>	
<p>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. <i>Sensitivity Test for a New User:</i> Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.</p>	
<p>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</p>	
<p>Other Information: Protect this product from excessive heat and direct sun.</p>	
<p>Questions or Comments: Toll Free within USA 833-93-ENWIO</p>	

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

B.P.O. 5% CLEANSER
 Benzoyl Peroxide Acne Treatment
 1.5 fl.oz./44 mL

EN.0101

envio™
skin

PRINCIPAL DISPLAY PANEL - 14 g Tube Label

envio™
skin

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

0.5 oz/14 g

Drug Facts

Active Ingredients

Salicylic Acid 2%.....Acne Gel Treatment

Purpose

Acne Gel Treatment

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 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 Alternifolia (Tea Tree) Leaf Oil, Allantoin, Panthenol, Xanthan Gum, Glyceryl Stearate, Glyceryl Stearate Citrate, Lavandula Hybrid (Lavender Grosso) Oil*, Salix Alba (Willow) Bark Extract, Camellia Sinensis (Green Tea) Leaf Extract*, Ethylhexylglycerin, Phenoxethanol
*Certified Organic Ingredients

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

Questions? Toll Free within USA 833-93-ENVIO

Directions:

Apply evenly to affected area and allow to dry completely. Can be used twice daily or as directed by a physician.

Active Ingredient:

2% Salicylic Acid

Warnings:

For external use only. Avoid contact with the eyes, lips and mouth. 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. For full drug facts information, please refer to drug facts insert.

Questions?

Toll Free within USA 833-93-ENVIO

envioskin.com

Dist. By: Smart Skin Health, LLC

Naples, FL 34108

Manufactured in the USA

Free of Fragrance, Parabens,

Sulfates, Phthalates

Please Recycle ♻️ EN.0201

S.A. 2% GEL SERUM

Salicylic Acid Acne Treatment

0.5 oz/14 g

envio[™]
skin

ENVIO 30 DAY DAILY ESSENTIALS DUO

benzoyl peroxide and salicylic acid kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81252-1000
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81252-1000-1	1 in 1 CARTON	10/21/2021	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	44 mL
Part 2	1 TUBE	14 g
Part 3	1 TUBE	30 g

Part 1 of 3

B.P.O. CLEANSER

benzoyl peroxide gel

Product Information

Item Code (Source) NDC:81252-0101

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: 059QF0K00R)	
Sodium C14-16 Olefin Sulfonate (UNII: O9W3D3YF5U)	
Glycerin (UNII: PDC6A3C0OX)	
Cocamidopropyl Betaine (UNII: 5OCF3O11KX)	
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81252-0101-1	44 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 3

S.A. SERUM

salicylic acid gel

Product Information

Item Code (Source)	NDC:81252-0201
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	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: PDC6A3C00X)	
Decyl Glucoside (UNII: Z17H97EA6Y)	
Witch Hazel (UNII: 101I4J0U34)	
Tea Tree Oil (UNII: VIF565UC2G)	
Allantoin (UNII: 344S277G0Z)	
Panthenol (UNII: WW9CM0O67Z)	
Xanthan Gum (UNII: TTV12P4NEE)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Glyceryl Stearate Citrate (UNII: WH8T92A065)	
Salix Alba Bark (UNII: 205MXS71H7)	
Green Tea Leaf (UNII: WZZU1RY8B0)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Phenoxyethanol (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81252-0201-1	14 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 FINAL	part333D	10/21/2021	

Part 3 of 3

CLARIFYING CLAY MASK

paste masks (mud packs) paste

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	Water (UNII: 059QF0KO0R)	
INGR	Glycerin (UNII: PDC6A3C0OX)	
INGR	Bentonite (UNII: A3N5ZCN45C)	
INGR	Kaolin (UNII: 24H4NWX5CO)	
INGR	Glyceryl Ricinoleate (UNII: ZUE0CEL42O)	
INGR	Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
INGR	Stearic Acid (UNII: 4ELV7Z65AP)	
INGR	Alcohol (UNII: 3K9958V90M)	
INGR	Cetyl Alcohol (UNII: 936JST6JCN)	
INGR	Titanium Dioxide (UNII: 15FIX9V2JP)	
INGR	Cranberry (UNII: 0MVO31Q3QS)	
INGR	Salix Alba Bark (UNII: 205MXS71H7)	
INGR	Passiflora Incarnata Flower (UNII: K8F3G29S6Z)	
INGR	Chamomile (UNII: FGL3685T2X)	
INGR	Calendula Officinalis Flower (UNII: P0M7O4Y7YD)	
INGR	Rosemary Oil (UNII: 8LGU7VM393)	
INGR	Lonicera Japonica Flower (UNII: 4465L2WS4Y)	
INGR	Lonicera Caprifolium Flower (UNII: 5N1WD9784U)	
INGR	.Alpha.-Tocopherol Acetate, D- (UNII: A7E6112E4N)	
INGR	Allantoin (UNII: 344S277G0Z)	
INGR	Glycol Distearate (UNII: 13W7MDN21W)	
INGR	Glyceryl Monostearate (UNII: 230OU9XXE4)	
INGR	Cocamidopropyl Hydroxysultaine (UNII: 62V75NI93W)	
INGR	Dimethicone (UNII: 92RU3N3Y1O)	
INGR	Caprylyl Glycol (UNII: 00YIU5438U)	
INGR	Xanthan Gum (UNII: TTV12P4NEE)	
INGR	Fytic Acid (UNII: 7IGF0S7R8I)	
INGR	Maltodextrin (UNII: 7CVR7L4A2D)	
INGR	Citric Acid Monohydrate (UNII: 2968PHW8QP)	
INGR	Trisodium Ethylenediamine Disuccinate (UNII: YA22H34H9Q)	
INGR	Carbomer Homopolymer, Unspecified Type (UNII: 0A5MM307FC)	
INGR	PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
INGR	Sodium Hydroxide (UNII: 55X04QC32I)	
INGR	Potassium Sorbate (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 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
COSMETIC		10/21/2021	

Marketing Information

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