

ACNE WIPEOUT CLINICAL ACNE SYSTEM- benzoyl peroxide
University Medical Pharmaceuticals Corp.

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.

ACNE WIPEOUT® CLINICAL ACNE SYSTEM

ACNE WIPEOUT ALL DAY BREAKOUT CONTROL

Drug Facts

Active ingredient

Benzoyl Peroxide 5% w/v

Purpose

Acne treatment

Use

- For the treatment of acne

Warnings

For external use only.

Do not use • If you are sensitive to Benzoyl Peroxide or have very sensitive skin. This product may cause irritation. Ask a doctor or pharmacist before use • If you are using other topical acne drugs at the same time or right after use of this product. This may increase dryness, redness or irritation of the skin. If this occurs, only one medication should be used unless a doctor directs otherwise.

When using this product • Avoid contact with eyes. If contact occurs, flush thoroughly with water. Keep away from lips and mouth. • Avoid unnecessary sun exposure and use a sunscreen. • Avoid product contact with hair and dyed fabrics, including towels, carpets and clothing which may be bleached by this product.

Stop use and ask a doctor if

- if excessive irritation occurs.

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

Directions

Adults and children 12 years of age and older:

Use every morning after cleansing with Acne Wipeout™ Clear Pore Oil-Free Cleanser. Apply a dime-size amount to clean skin, avoiding the eye area. Do not rinse. If bothersome dryness or irritation occurs, reduce frequency of use.

Other information

- store at room temperature (68° to 77° F)
- Protect from freezing

Inactive Ingredients

Water (Aqua), Sodium C14-16 Olefin Sulfonate, PEG-8, Disodium Laureth Sulfosuccinate, Polyacrylate-1 Crosspolymer, Cocamidopropyl Betaine, Allyl Methacrylates Crosspolymer, Butylene Glycol, Glycerin, DMDM Hydantoin, Tocopheryl Acetate (Vitamin E Acetate), Glycyrrhiza Glabra (Licorice) Root Extract, Calendula Officinalis Flower Extract, Hamamelis Virginiana (Witch Hazel) Extract, Citric Acid, Tetrasodium EDTA, Sodium Hydroxide, Fragrance, Sodium Benzotriazolyl Butylphenol Sulfonate, Benzoic Acid.

Questions? Call toll free 855-299-8800

ACNE WIPEOUT CLEAR PORE OIL-FREE CLEANSER

Drug Facts

Active ingredient

Benzoyl Peroxide 2.5% w/v

Purpose

Acne treatment

Use

- For the treatment of acne

Warnings

For external use only.

Do not use • If you are sensitive to Benzoyl Peroxide or have very sensitive skin. This product may cause irritation. Ask a doctor or pharmacist before use • If you are using other topical acne drugs at the same time or right after use of this product. This may increase dryness, redness or irritation of the skin. If this occurs, only one medication should be used unless a doctor directs otherwise.

When using this product • Avoid contact with eyes. If contact occurs, flush thoroughly with water. Keep away from lips and mouth. • Avoid unnecessary sun exposure and use a sunscreen. • Avoid product contact with hair and dyed fabrics, including towels, carpets and clothing which may be bleached by this product.

Stop use and ask a doctor if

- excessive irritation occurs.

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

Directions

Adults and children 12 years of age and older:

Use every morning and evening. Apply to damp skin and gently massage, avoiding the eye area. Rinse well. If bothersome dryness or irritation occurs, reduce frequency of use.

Other information

- store at room temperature (68° to 77° F)
- Protect from freezing

Inactive Ingredients

Carbomer, Ethylhexylglycerin, Jojoba Esters, Phenoxyethanol, Sodium Hydroxide, Water, Silica, Sodium Dioctyl Sulfosuccinate, Xanthan Gum, 1,3 Propanediol, Dimethicone, PEG-40 Stearate.

Questions? Call toll free 855-299-8800

ACNE WIPEOUT TIME-RELEASED RETINOL PLUS NIGHT CREAM

Warnings

For external use only.

Avoid contact with eyes. If contact occurs, flush thoroughly with water. Keep away from lips and mouth.

Sunburn Alert

Use a sunscreen, wear protective clothing and limit sun exposure while using this product.

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

Directions

Use only at night. Apply to face after cleansing with Acne Wipeout™ Clear Pore Oil-Free Cleanser. Do not rinse. **Limit sun exposure, and use sunscreen when going outdoors.** Formulated to minimize irritation. If any irritation occurs, reduce frequency of use.

Ingredients

Caprylic/Capric Triglyceride, Glycerin, Silica, Cetearyl Alcohol, Butyrospermum Parkii (Shea) Butter, Glyceryl Stearate, Retinol, Ceramide-3, Chlorhexidine Gluconate, polysorbate 20, Laureth-23, Cetyl Palmitate, Trideceth-6 Phosphate, Pentylene Glycol, Dimethicone, Ceteareth-20, Carbomer, Sodium Hydroxide, PPG-12 SMDI Copolymer, PEG-100 Stearate, Phenoxyethanol, Disodium EDTA, Ethylhexylglycerin

Questions? call toll free 855-299-8800

DERMATOLOGICAL FIRST LINE ACNE CARE

HIGH SPEED CLEARING

RESULT START IN 1 HOUR MINIMIZES DRYNESS AND IRRITATION

24/7 TIME-RELEASED RETINOID + BENZOYL PEROXIDE COMBINATION THERAPY

ALL DAY BREAKOUT CONTROL 2 FL OZ (60ML)

CLEAR PORE OIL-FREE CLEANSER 4 FL OZ (120 ML)

TIME RELEASED RETINOL+ 1 FL OZ (30ML)

**AMERICAN ACADEMY OF DERMATOLOGY FIRST LINE ACNE MEDICATIONS
TOPICAL RETINOID + BENZOYL PEROXIDE**

ANTI-INFLAMMATORY

ANTIBACTERIAL

NON-COMEDOGENIC

COMPARE TO **PROACTIV MD®**

COMBINATION THERAPY

Our topical retinoid and benzoyl peroxide work together day and night to target both inflammatory and comedonal acne quickly and effectively. So you can get clear faster.

TIME-RELEASED

Minimizes irritation and speeds up results with time-released actives.

DAY

All Day Breakout Control delivers time-released benzoyl peroxide into pores to kill acne bacteria on contact, and all day.

NIGHT

A natural alternative to Adapalene, Time-Released Retinol+ works all night to unclog pores, essential for benzoyl peroxide to work effectively.

TIME-RELEASED

All Day Breakout Control delivers micronized, time-released benzoyl peroxide into pores to kill acne bacteria all day long—while hydrating skin and minimizing irritation and dryness.

GENTLE EXFOLIATING

Gently clears pores to deliver medication as you clean, controls shine, calms redness and leaves skin feeling soft and smooth.

NATURAL RETINOID ALTERNATIVE TO ADAPALENE

Retinol+ is a natural retinoid enhanced for increased speed and effectiveness, plus time-released to minimize dryness and irritation.

acnewipeout.com

made in usa

UNIVERSITY MEDICAL

PHARMACEUTICALS CORP

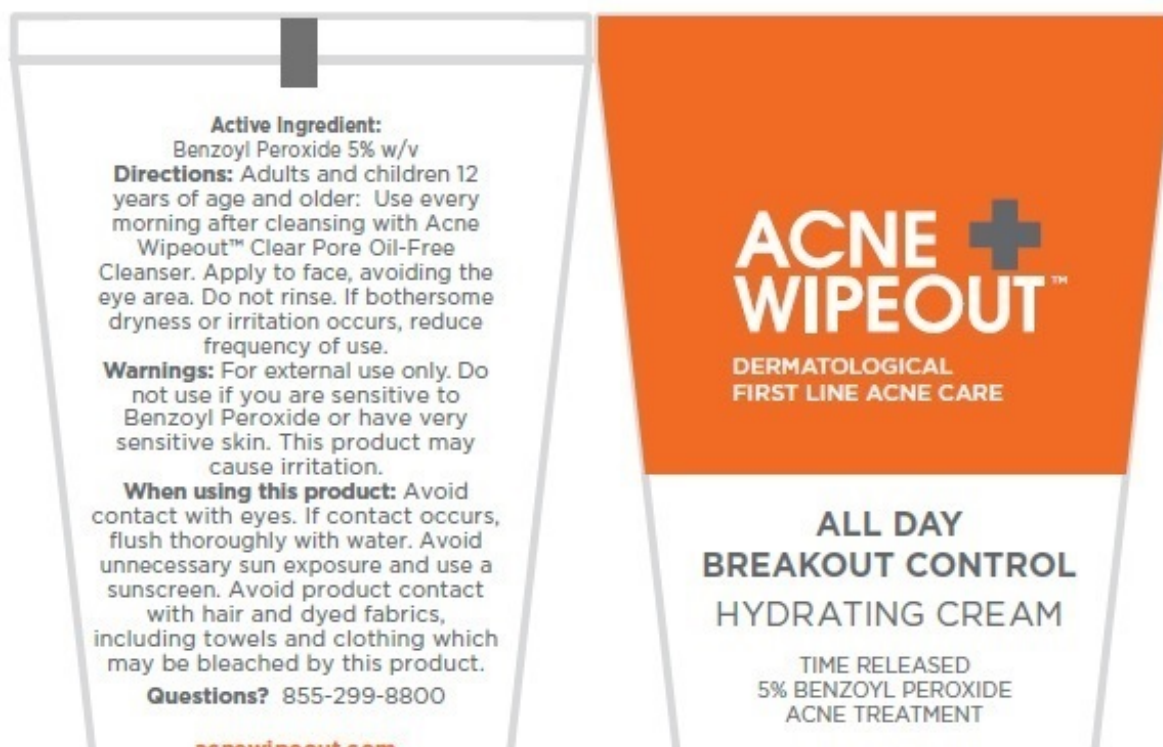
9671 Irvine Center Drive

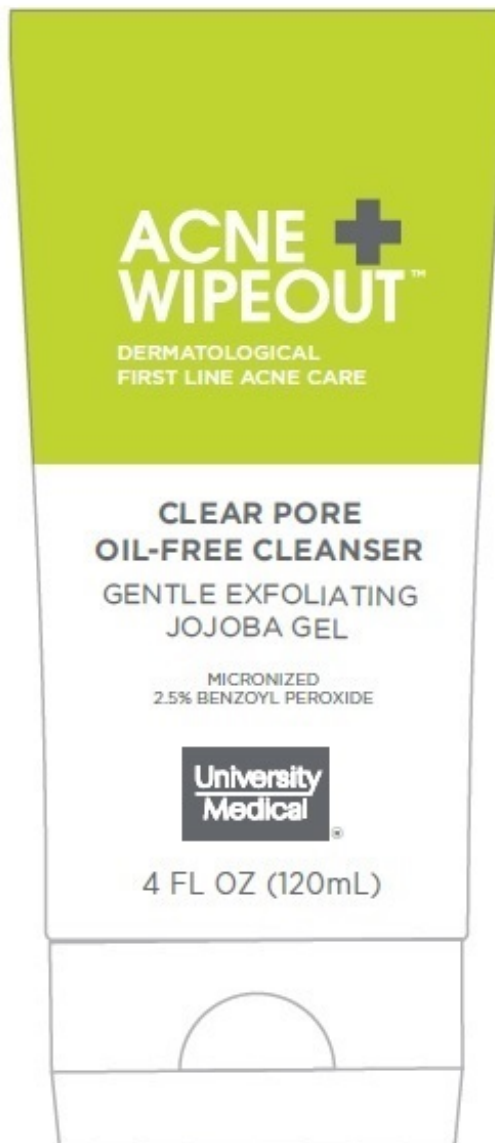
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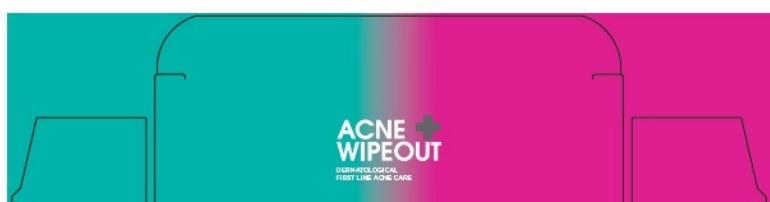
Packaging

KIT COMPONENTS LABEL





KIT LABEL



TIME-RELEASED
All Day Breakout Control delivers retinol, time-released benzoyl peroxide into pores to kill acne bacteria all day long—while hydrating skin and relieving inflammation.

GENTLE EXFOLIATING
Gently clears pores to deliver medication as you clean, controls shine, calms redness and leaves skin feeling soft and smooth.

NATURAL RETINOID ALTERNATIVE TO ADAPALENE
Retinol is a natural retinoid enhanced for increased speed and effectiveness, plus time-released to reduce dryness and irritation.

NEW

ACNE WIPEOUT[®]

DERMATOLOGICAL FIRST LINE ACNE CARE

HIGH SPEED CLEARING

COMPARE TO PROACTIV MD.

COMBINATION THERAPY
Our topical retinoid and benzoyl peroxide work together day and night to target both inflammatory and comedonal acne quickly and effectively, so you can get clear faster.

TIME-RELEASED
Minimizes irritation and speeds up results with time-released actives.

DAY
All Day Breakout Control delivers time-released benzoyl peroxide into pores to kill acne bacteria on contact, and all day.

NIGHT
A natural alternative to Adapalene, Time-Released Retinol⁺ works all night to unclog pores, essential for benzoyl peroxide to work effectively.

ALL DAY BREAKOUT CONTROL

Drug Facts	Purpose
Active ingredient: Benzoyl Peroxide 5% w/v	Acne treatment
Use: For the treatment of acne	
Warnings: For external use only	
Directions: Use every morning after cleansing with Acne Wipeout [™] Clear Pore Oil-Free Cleanser. Apply a dime-size amount to clean skin, avoiding the eye area. Do not rinse. If bothersome dryness or irritation occurs, reduce frequency of use. May be applied all over face to help control future breakouts.	
Other information: store at room temperature (68° to 77° F) Protect from freezing	
Inactive Ingredients: Water (Aqua), Sodium C14-16 Olefin Sulfonate, PEG-8, Disodium Laureth Sulfosuccinate, Polyacrylate-1 Crosspolymer, Cocamidopropyl Betaine, Allyl Methacrylates Crosspolymer, Butylene Glycol, Glycerin, DMDM Hydantoin, Tocopheryl Acetate (Vitamin E Acetate), Glycyrrhiza Glabra (Licorice) Root Extract, Calendula Officinalis Flower Extract, Hamamelis Virginiana (Witch Hazel) Extract, Citric Acid, Tetrasodium EDTA, Sodium Hydroxide, Fragrance, Sodium Benzotriazoyl Butylphenol Sulfonate, Benzolol Acid.	
Questions? Call toll free 855-299-8800	

CLEAR PORE OIL-FREE CLEANSER

Drug Facts	Purpose
Active ingredient: Benzoyl Peroxide 2.5% w/v	Acne treatment
Use: For the treatment of acne	
Warnings: For external use only	
Directions: Use every morning and evening. Apply to damp skin and gently massage, avoiding the eye area. Rinse well. If bothersome dryness or irritation occurs, reduce frequency of use.	
Other information: store at room temperature (68° to 77° F) Protect from freezing	
Inactive Ingredients: Carbomer, Ethylhexylglycerin, Jojoba Esters, Phenoxyethanol, Sodium Hydroxide, Water, Silica, Sodium Dodecyl Sulfosuccinate, Xanthan Gum, 1,3 Propanediol, Dimethylcone, PEG-40 Stearate.	
Questions? Call toll free 855-299-8800	

TIME-RELEASED RETINOL⁺

Drug Facts	Purpose
Active ingredient: Retinol	Acne treatment
Use: For the treatment of acne	
Warnings: For external use only	
Directions: Use every morning and evening. Apply to damp skin and gently massage, avoiding the eye area. Rinse well. If bothersome dryness or irritation occurs, reduce frequency of use.	
Other information: store at room temperature (68° to 77° F) Protect from freezing	
Inactive Ingredients: Carbomer, Ethylhexylglycerin, Jojoba Esters, Phenoxyethanol, Sodium Hydroxide, Water, Silica, Sodium Dodecyl Sulfosuccinate, Xanthan Gum, 1,3 Propanediol, Dimethylcone, PEG-40 Stearate.	
Questions? Call toll free 855-299-8800	

AMERICAN ACADEMY OF DERMATOLOGY FIRST LINE ACNE MEDICATIONS: TOPICAL RETINOID + BENZOYL PEROXIDE

ANTI-INFLAMMATORY ANTIBACTERIAL NON-COMEDOGENIC

CLINICAL ACNE SYSTEM

RESULT START IN 1 HOUR MINIMIZES DRYNESS AND IRRITATION

24/7 TIME-RELEASED RETINOID + BENZOYL PEROXIDE COMBINATION THERAPY

ALL DAY BREAKOUT CONTROL 2 FL OZ (60ML)

CLEAR PORE OIL-FREE CLEANSER 4 FL OZ (120 ML)

TIME RELEASED RETINOL⁺ 1 FL OZ (30ML)

University Medical

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DRUG FACTS LABEL

ALL DAY BREAKOUT CONTROL

Drug Facts	
Active ingredient	Purpose
Benzoyl Peroxide 5% w/v.....	Acne treatment
Use ■ For the treatment of acne	
Warnings For external use only.	
Do not use ■ If you are sensitive to Benzoyl Peroxide or have very sensitive skin. This product may cause irritation. Ask a doctor or pharmacist before use ■ If you are using other topical acne drugs at the same time or right after use of this product. This may increase dryness, redness or irritation of the skin. If this occurs, only one medication should be used unless a doctor directs otherwise. When using this product ■ Avoid contact with eyes. If contact occurs, flush thoroughly with water. Keep away from lips and mouth. ■ Avoid unnecessary sun exposure and use a sunscreen. ■ Avoid product contact with hair and dyed fabrics, including towels, carpets and clothing which may be bleached by this product.	
Stop use and ask a doctor if ■ excessive irritation occurs.	
Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center immediately.	
Directions Adults and children 12 years of age and older: Use every morning after cleansing with Acne Wipeout [™] Clear Pore Oil-Free Cleanser. Apply a dime-size amount to clean skin, avoiding the eye area. Do not rinse. If bothersome dryness or irritation occurs, reduce frequency of use. May be applied all over face to help control future breakouts.	
Other information ■ store at room temperature (68° to 77° F) ■ Protect from freezing	
Inactive Ingredients Water (Aqua), Sodium C14-16 Olefin Sulfonate, PEG-8, Disodium Laureth Sulfosuccinate, Polyacrylate-1 Crosspolymer, Cocamidopropyl Betaine, Allyl Methacrylates Crosspolymer, Butylene Glycol, Glycerin, DMDM Hydantoin, Tocopheryl Acetate (Vitamin E Acetate), Glycyrrhiza Glabra (Licorice) Root Extract, Calendula Officinalis Flower Extract, Hamamelis Virginiana (Witch Hazel) Extract, Citric Acid, Tetrasodium EDTA, Sodium Hydroxide, Fragrance, Sodium Benzotriazoyl Butylphenol Sulfonate, Benzolol Acid.	
Questions? Call toll free 855-299-8800	

CLEAR PORE OIL-FREE CLEANSER

Drug Facts	
Active ingredient	Purpose
Benzoyl Peroxide 2.5% w/v.....	Acne treatment
Use ■ For the treatment of acne	
Warnings For external use only.	
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Other information ■ store at room temperature (68° to 77° F) ■ Protect from freezing	
Inactive Ingredients Carbomer, Ethylhexylglycerin, Jojoba Esters, Phenoxyethanol, Sodium Hydroxide, Water, Silica, Sodium Dodecyl Sulfosuccinate, Xanthan Gum, 1,3 Propanediol, Dimethylcone, PEG-40 Stearate.	
Questions? Call toll free 855-299-8800	

TIME-RELEASED RETINOL⁺

Warnings
For external use only. Avoid contact with eyes. If contact occurs, flush thoroughly with water. Keep away from lips and mouth.
Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center immediately.
Sunburn Alert Use a sunscreen, wear protective clothing and limit sun exposure while using this product.
Directions Use only at night. Apply to face after cleansing with Acne Wipeout [™] Clear Pore Oil-Free Cleanser. Do not rinse. Limit sun exposure, and use sunscreen when going outdoors. Formulated to minimize irritation. If any irritation occurs, reduce frequency of use.
Ingredients Caprylic/Capric Triglyceride, Glycerin, Silica, Cetearyl Alcohol, Butyrospermum Parkii (Shea) Butter, Glyceryl Stearate, Retinol, Ceramide-3, Chlorhexidine Gluconate, Polysorbate 20, Laureth-23, Cetyl Palmitate, Trideceth-6 Phosphate, Pentylene Glycol, Dimethylcone, Ceteareth-20, Carbomer, Sodium Hydroxide, PPG-12 SMDI Copolymer, PEG-100 Stearate, Phenoxyethanol, Disodium EDTA, Ethylhexylglycerin.
Questions? Call toll free 855-299-8800

ACNE WIPEOUT[®] CLINICAL ACNE SYSTEM

benzoyl peroxide kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50544-150
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50544-150-44	1 in 1 KIT; Type 0: Not a Combination Product	06/01/2020	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	60 mL
Part 2	1 TUBE	120 mL
Part 3	1 TUBE	30 mL

Part 1 of 3

ACNE WIPEOUT ALL DAY BREAKOUT CONTROL

benzoyl peroxide cream

Product Information

Item Code (Source)	NDC:50544-152
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
DISODIUM LAURETH SULFOSUCCINATE (UNII: D6DH1DTN7E)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
ALLYL METHACRYLATE/GLYCOL DIMETHACRYLATE CROSSPOLYMER (UNII: B9J55EA6QX)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
GLYCERIN (UNII: PDC6A3C0OX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SODIUM BENZOTRIAZOLYL BUTYLPHENOL SULFONATE (UNII: 0LA2QC9O3Z)	
BENZOIC ACID (UNII: 8SKN0B0MIM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		60 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	06/01/2020	

Part 2 of 3

ACNE WIPEOUT CLEAR PORE OIL-FREE CLEANSER

benzoyl peroxide gel

Product Information

Item Code (Source)	NDC:50544-151
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	2.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
JOJOBA OIL (UNII: 724GKU717M)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

WATER (UNII: 059QF0KO0R)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PROPANEDIOL (UNII: 5965N8W85T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	

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Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		120 mL in 1 TUBE; Type 0: Not a Combination Product		

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Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	06/01/2020	

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Part 3 of 3
ACNE WIPEOUT TIME-RELEASED RETINOL PLUS NIGHT CREAM face and neck (excluding shaving preparations)

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Product Information

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Other Ingredients		
Ingredient Kind	Ingredient Name	Quantity
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	SHEA BUTTER (UNII: K49155WL9Y)	
INGR	GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
INGR	RETINOL (UNII: G2SH0XKK91)	
INGR	CERAMIDE NP (UNII: 4370DF050B)	
INGR	CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
INGR	POLYSORBATE 20 (UNII: 7T1F30V5YH)	
INGR	LAURETH-23 (UNII: N72LMW566G)	
INGR	CETYL PALMITATE (UNII: 5ZA2S6B08X)	
INGR	TRIDECETH-6 PHOSPHATE (UNII: NKT96BX1OC)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	

INGR	POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
INGR	CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	PPG-12/SMDI COPOLYMER (UNII: 1BK9DDD24E)	
INGR	PEG-100 STEARATE (UNII: YD01N1999R)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 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
Cosmetic		06/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	06/01/2020	

Labeler - University Medical Pharmaceuticals Corp. (809706252)

Revised: 10/2020

University Medical Pharmaceuticals Corp.