

**PROACTIV MD KIT- md kit**  
**Alchemee, LLC**

-----  
**Proactiv MD Kit**

**Adapalene Gel 0.1% - Drug Facts**

***Drug Facts***

***Adapalene Gel 0.1% - Active ingredient***

Adapalene Gel 0.1% (retinoid)

***Adapalene Gel 0.1% - Purpose***

Acne treatment

***Adapalene Gel 0.1% - Use***

for the treatment of acne

***Adapalene Gel 0.1% - Warnings***

**For external use only**

**Do not use**

- on damaged skin (cuts, abrasions, eczema, sunburn)
- if you're allergic to adapalene or any of the ingredients in this product

**Adapalene Gel 0.1% - When using this product**

- limit sun exposure, including light from tanning beds, and use sunscreen when going outdoors
- do not wax to remove hair in areas where the product has been applied
- during the early weeks of use, your acne may appear to worsen before it improves (this is normal); continue using as directed, unless you get irritation that becomes severe
  - irritation (redness, itching, dryness, burning) is more likely to occur:
    - in the first few weeks of use
    - if using more than one topical acne medication at a time
    - but irritation usually lessens with continued use of this product
    - it may take up to 3 months of once daily use to see results
    - avoid product contact with eyes, lips, and mouth. If contact occurs, immediately flush the area with water.
    - wash hands after use

**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.

### **Adapalene Gel 0.1% - Keep out of reach of children**

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

### **Adapalene Gel 0.1% - Directions**

Adults and children 12 years of age and older:

- use once daily
- clean the skin gently and pat dry before applying the product
- cover the entire affected area with a thin layer. For example, if your acne is on the face, apply the product to the entire face.
- do not use more than one time a day. Applying more than directed will not provide faster or better results, but may worsen skin irritation.

Children under 12 years of age: ask a doctor

### **Adapalene Gel 0.1% - Other information**

- Store at room temperature 68o – 77oF
- protect from freezing

### **Adapalene Gel 0.1% - Inactive ingredients**

carbomer, disodium EDTA, phenoxyethanol, poloxamer 182, propylene glycol, sodium hydroxide, water

### **Questions or comments?**

1-800-950-4695

Distributed by Alchemee LLC

Santa Monica, CA 90401

Made in the USA of Foreign

and Domestic Components

Questions? 1-800-950-4695 • [proactiv.com](http://proactiv.com)

Proactiv is a registered trademark  
of Taro Pharmaceuticals U.S.A., Inc.

### **PRINCIPAL DISPLAY PANEL - ProactivMD Kit**

proactiv®

# ProactivMD

## 3-step acne treatment system

Featuring our prescription-strength retinoid

### Step 1: Cleanse

Washes away debris & oil

### Step 2: Treat

First FDA-approved over-the-counter topical retinoid\* for acne treatment

Previously available only by prescription.

Dermatologist developed and tested

\*Read carton and consumer leaflet information before using

### Step 3: Hydrate

Keeps skin hydrated & refreshed

Kit Contains: Ultra-Gentle Cleaner 2 FL. OZ. (60 mL) Adapalene Gel 0.1% 0.5 FL. OZ. (15 g) Ultra-Hydrating Moisturizer 1 FL. OZ. (30 mL)



The image shows three tubes of ProactivMD products: Ultra-Gentle Cleanser (2 FL. OZ. / 60 mL), Adapalene Gel 0.1% (0.5 FL. OZ. / 15 g), and Ultra-Hydrating Moisturizer (1 FL. OZ. / 30 mL). The tubes are white with teal accents and the ProactivMD logo. A teal banner at the top right says "For stubborn breakouts". A teal banner at the bottom left says "Get that clear skin feeling." Below this banner is a short paragraph: "Proactiv is different because we treat acne with effective, three-step systems. Our tried and true formulations work together cohesively to treat and prevent acne so you can get clear — and stay clear."

**proactiv<sup>®</sup>**

**ProactivMD.**  
3-step acne treatment system  
Featuring our prescription-strength retinoid

**Step 1: Cleanse**  
Washes away dirt & oil

**Step 2: Treat**  
First FDA-approved over-the-counter topical retinoid\* for acne treatment  
Previously available only by prescription.  
Dermatologist developed and tested  
\*Read carton and consumer leaflet information before using

**Step 3: Hydrate**  
Keeps skin hydrated & refreshed

For stubborn breakouts

Get that clear skin feeling.

Proactiv is different because we treat acne with effective, three-step systems. Our tried and true formulations work together cohesively to treat and prevent acne so you can get clear — and stay clear.

Actual size

Kit Contains: Ultra-Gentle Cleaner 2 FL. OZ. (60 mL) Adapalene Gel 0.1% 0.5 FL. OZ. (15 g) Ultra-Hydrating Moisturizer 1 FL. OZ. (30 mL)

Distributed by  
The Proactiv Company LLC.  
El Segundo, CA 90245  
Questions or comments?  
1-800-950-4695 • proactiv.com

**ProactivMD Ultra-Gentle Cleanser:**  
Made in Germany of Foreign and Domestic Components

**ProactivMD Ultra-Hydrating Moisturizer:**  
Made in the USA of Foreign and Domestic Components

**ProactivMD Adapalene:**  
Made in Canada of Foreign and Domestic Components

ProactivMD is a trademark of The Proactiv Company Sàrl.

♻️ Carton and inserts are 100% recyclable.

# ProactivMD

## 3-step acne treatment system

This trio is ideal for treating stubborn breakouts — and the redness and inflammation that often appear alongside them. Its star is **Adapalene Gel**: our prescription-strength formula that works on a cellular level to clear skin, which restores even tone and texture. And now it's available for you... no Rx required.

### Directions:

#### Ultra-Gentle Cleanser ☀️🌙

Use twice daily, morning and night. Wash your whole face avoiding eye area. Apply a generous amount to dampened skin and gently massage with fingertips for 1 to 2 minutes. Rinse thoroughly with warm water.

#### Adapalene Gel 0.1% 🌙

Adults and children 12 years of age and older: Use once daily. Clean the skin gently and pat dry before applying the product. Cover the entire affected area with a thin layer. Children under 12 years of age: ask a doctor.

#### Ultra-Hydrating Moisturizer ☀️🌙

Apply daily, as needed, to alleviate dryness. When applying after the Adapalene treatment, allow the treatment to dry completely before applying. Can be worn alone or under makeup. If going outside, wear a sunscreen SPF 30 or higher.

### Ultra-Gentle Cleanser

#### Ingredients:

water, cocamidopropyl betaine, glycerin, disodium cocoamphodiacetate, coco-glucoside, sodium chloride, acrylates/C10-30 alkyl acrylate crosspolymer, sodium cocoamphoacetate, panthenol, citric acid, phenoxyethanol, sodium benzoate, sodium citrate, heliotropine, tocopheryl acetate, xanthan gum, polyquaternium-10, coconut acid, sodium hydroxide, fragrance, camellia sinensis leaf extract

### Ultra-Hydrating Moisturizer

#### Ingredients:

water, butylene glycol, dimethicone, cetearyl alcohol, glycol stearate, glycerin, morus alba root extract, arctostaphylos uva ursi leaf extract, glycyrrhiza glabra (licorice) root extract, scutellaria baicalensis root extract, camellia sinensis leaf extract, safflower oil/palm oil aminopropanediol esters, kojic acid, sodium hyaluronate, sodium polyacrylate, ethylhexyl palmitate, cetareth-20, polysorbate 60, aluminum starch octenylsuccinate, hydrogenated polydecene, PPG-2 myristyl ether propionate, phenoxyethanol, squalane, caprylic/capric triglyceride, glycogen, caprylyl glycol, C12-15 alkyl lactate, ethylhexylglycerin, hexylene glycol, bisabolol, citric acid, PPG-5-laureth-5, disodium EDTA, polyquaternium-11, fragrance

### Adapalene Gel 0.1%

#### Drug Facts

Active ingredient	Purpose
Adapalene 0.1% (retinoid)*	Acne treatment

\*read consumer information leaflet

#### Use

- For the treatment of acne

#### Warnings

For external use only

#### Do not use

- on damaged skin (cuts, abrasions, eczema, sunburn)
- if you are allergic to adapalene or any of the ingredients in this product.

If pregnant or breast-feeding, ask a doctor before use.

#### When using this product

- limit sun exposure, including light from tanning beds, and use sunscreen when going outdoors
- do not wax to remove hair in areas where the product has been applied
- during the early weeks of use, your acne may appear to worsen before it improves (this is normal); continue using as directed, unless you get irritation that becomes severe
- irritation (redness, itching, dryness, burning) is more likely to occur:
  - in the first few weeks of use
  - if using more than one topical acne medication at a time
  - but irritation usually lessens with continued use of this product
- it may take up to 3 months of once daily use to see results
- avoid product contact with eyes, lips, and mouth. If contact occurs, immediately flush the area with water.
- wash hands after use

#### Stop use and ask a doctor if

- you become pregnant, or are planning to become pregnant, while using the product
- you have symptoms of an allergic reaction (such as itching, rash, hives, swelling of the lips, eyelids, and shortness of breath)
- irritation becomes severe
- you see no improvement after 3 months of once daily use

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

#### Directions

Adults and children 12 years of age and older:

- use once daily
- clean the skin gently and pat dry before applying the product
- cover the entire affected area with a thin layer. For example, if your acne is on the face, apply the product to the entire face.
- do not use more than one time a day. Applying more than directed will not provide faster or better results, but may worsen skin irritation.

Children under 12 years of age: ask a doctor

#### Other information

- store at room temperature 68°-77°F
- protect from freezing

**Inactive ingredients** carbomer 940, edetate disodium, methylparaben, poloxamer 182, propylene glycol, purified water and sodium hydroxide. May contain hydrochloric acid to adjust pH.

**Questions?** 1-800-950-4895

Once Daily Topical Retinoid\*  
\*Read Consumer Information leaflet before use

## PROACTIV MD KIT

md kit kit

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11410-224
--------------	----------------	--------------------	---------------

### Packaging

#	Item Code	Package Description	Marketing Start	Marketing End
---	-----------	---------------------	-----------------	---------------

#	Item Code	Package Description	Date	Date
1	NDC:11410-224-30	1 in 1 BOX; Type 0: Not a Combination Product	05/08/2024	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	60 mL in 100
Part 2	1 TUBE	15 g in 100
Part 3	1 TUBE	30 mL in 100

### Part 1 of 3

#### PROACTIV MD ULTRA-GENTLE CLEANSER

cleansing (cold creams, cleansing lotions, liquids, and pads) [skin care preparations (creams, lotions, powder, and sprays)] liquid

### Product Information

Route of Administration TOPICAL

### Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
INGR	<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
INGR	<b>GLYCERIN</b> (UNII: PDC6A3C00X)	
INGR	<b>COCO-GLUCOSIDE</b> (UNII: ICS790225B)	
INGR	<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
INGR	<b>WATER</b> (UNII: 059QF0KO0R)	
INGR	<b>DISODIUM COCOAMPHODIACETATE</b> (UNII: 18L9G3U51M)	
INGR	<b>PANTHENOL</b> (UNII: WW9CM0O67Z)	
INGR	<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>SODIUM COCOAMPHOACETATE</b> (UNII: W7Q5E87674)	
INGR	<b>ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER (60000 MPA.S AT 1.0%)</b> (UNII: 8Z5ZAL5H3V)	
INGR	<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
INGR	<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
INGR	<b>COCONUT ACID</b> (UNII: 40U37V505D)	
INGR	<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
INGR	<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
INGR	<b>HELIOTROPINE BUTANE-2,3-DIOL ACETAL</b> (UNII: 7Y4ZV19ZDP)	
INGR	<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
INGR	<b>POLYQUATERNIUM-10 (1000 MPA.S AT 2%)</b> (UNII: GMR4PEN8PK)	
INGR	<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	

## 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
Cosmetic		07/12/2024	

## Part 2 of 3

### PROACTIV MD ADAPALENE ACNE TREATMENT

adapalene gel

## Product Information

Item Code (Source)	NDC:11410-958
Route of Administration	TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ADAPALENE (UNII: 1L4806J2QF) (ADAPALENE - UNII:1L4806J2QF)	ADAPALENE	0.1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLOXAMER 182 (UNII: JX0HIX6OAG)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410-958-15	1 in 1 BOX		

1	15 g in 1 TUBE; Type 1: Convenience Kit of Co-Package	
---	---	--

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA215940	05/08/2024	

## Part 3 of 3

### PROACTIV MD ULTRA-HYDRATING MOISTURIZER

moisturizing [skin care preparations (creams, lotions, powder, and sprays)] cream

## Product Information

Route of Administration TOPICAL

## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	ETHYLHEXYL PALMITATE (UNII: 2865993309)	
INGR	HYDROGENATED POLYDECENE TYPE I (UNII: U333RI6EB7)	
INGR	LEVOMENOL (UNII: 24WE03BX2T)	
INGR	GLYCOGEN (UNII: 309GSC92U1)	
INGR	ARCTOSTAPHYLOS UVA-URSI LEAF (UNII: 3M5V3D1X36)	
INGR	MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
INGR	ALUMINUM STARCH OCTENYLSUCCINATE (UNII: I9PJ006294)	
INGR	PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
INGR	MORUS ALBA ROOT (UNII: CST1G9BZGD)	
INGR	ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
INGR	HYDROGENATED PALM/PALM KERNEL OIL PEG-6 ESTERS (UNII: 8EPU9MJ01K)	
INGR	GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
INGR	POLYSORBATE 60 (UNII: CAL22UVI4M)	
INGR	HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
INGR	POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
INGR	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
INGR	DIMETHICONE (UNII: 92RU3N3Y1O)	
INGR	GLYCERIN (UNII: PDC6A3C0OX)	
INGR	SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JN12J)	
INGR	GLYCOL STEARATE (UNII: 0324G66D0E)	
INGR	KOJIC ACID (UNII: 6K23F1TT52)	
INGR	CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
INGR	SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	WATER (UNII: 059QF0KO0R)	

INGR	<b>POLYQUATERNIUM-11 (1000000 MW)</b> (UNII: 0B44BS5IJS)	
INGR	<b>GLYCYRRHIZA GLABRA</b> (UNII: 2788Z9758H)	
INGR	<b>DOCUSATE SODIUM/SODIUM BENZOATE</b> (UNII: 656HXR6YXN)	
INGR	<b>SQUALANE</b> (UNII: GW89575KF9)	
INGR	<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
INGR	<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
INGR	<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	
INGR	<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)	
INGR	<b>C12-15 ALKYL LACTATE</b> (UNII: GC844VRD7E)	

### 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		11/01/2011	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M006	05/08/2024	

**Labeler** - Alchemee, LLC (080216357)

### Establishment

Name	Address	ID/FEI	Business Operations
kdc/one chatsworth, Inc.		118542196	manufacture(11410-224)

### Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(11410-224)

### Establishment

Name	Address	ID/FEI	Business Operations
VEE PAK, LCC		874763303	manufacture(11410-224)