

PROACTIV MD ADAPALENE ACNE TREATMENT- adapalene gel
Alchemee, LLC

Proactiv MD ® Adapalene Gel 0.1%
Acne Treatment

Drug Facts

Active ingredient

Adapalene 0.1% (retinoid) ¹

¹ read consumer information leaflet

Purpose

Acne treatment

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

- TAMPER EVIDENTI DONOT USE IF THE SEAL ON THE TUBE IS PUNCTURED OR VISIBLE.
- store at 20° to 25°C (68°- 77°F) (see USP Controlled Room Temperature).
- protect from freezing

Inactive ingredients

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

Distributed by Alchemee LLC,
Hawthorne, NY 10532

Made in Canada of Foreign
and Domestic Components

Questions?

1-800-950-4695

PRINCIPAL DISPLAY PANEL - 45 g Tube Box

proactivMD ®

ADAPALENE GEL 0.1%

ACNE TREATMENT

PARABEN-FREE

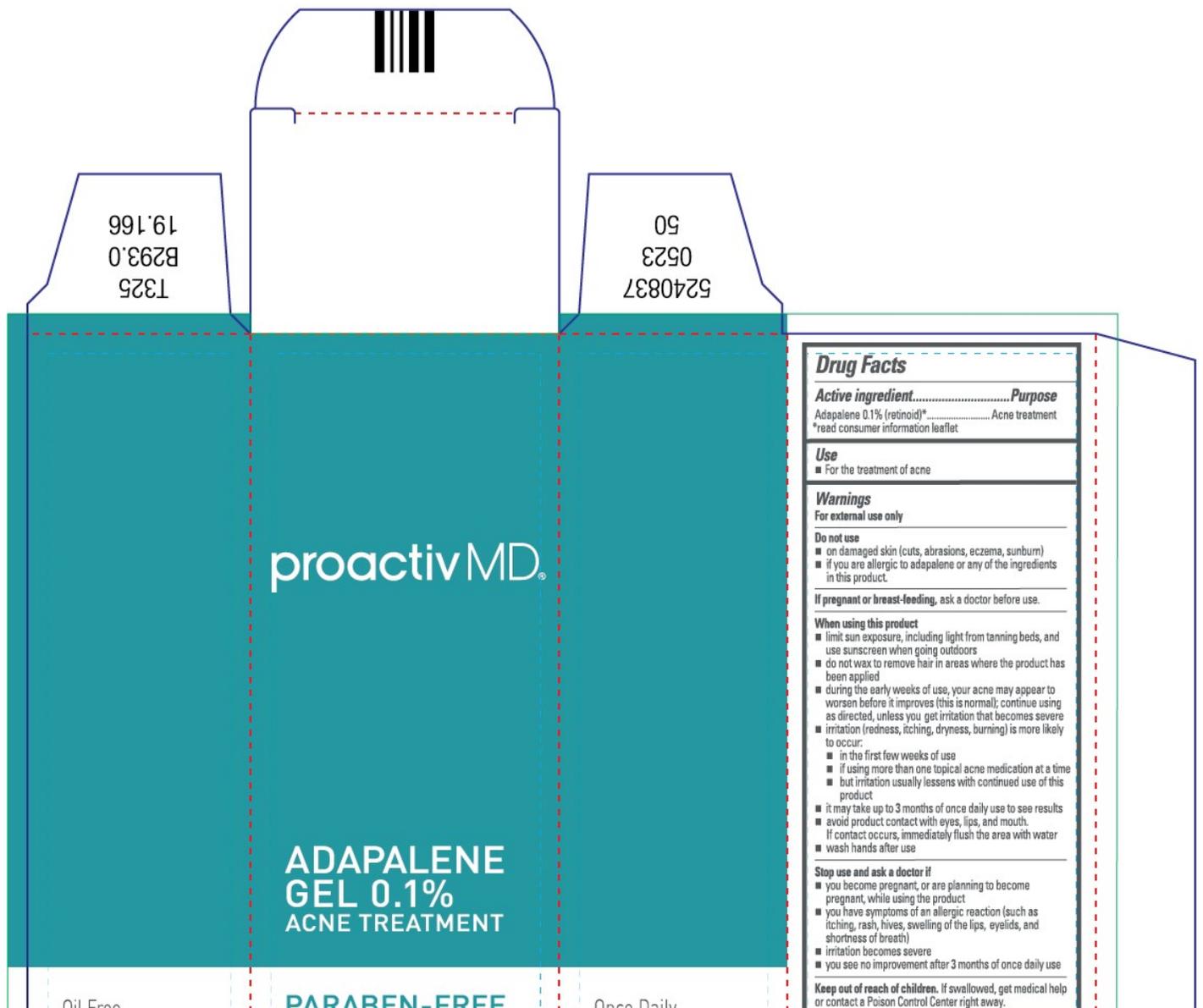
First FDA-Approved
Over-the-Counter
Topical Retinoid* for
Acne Treatment

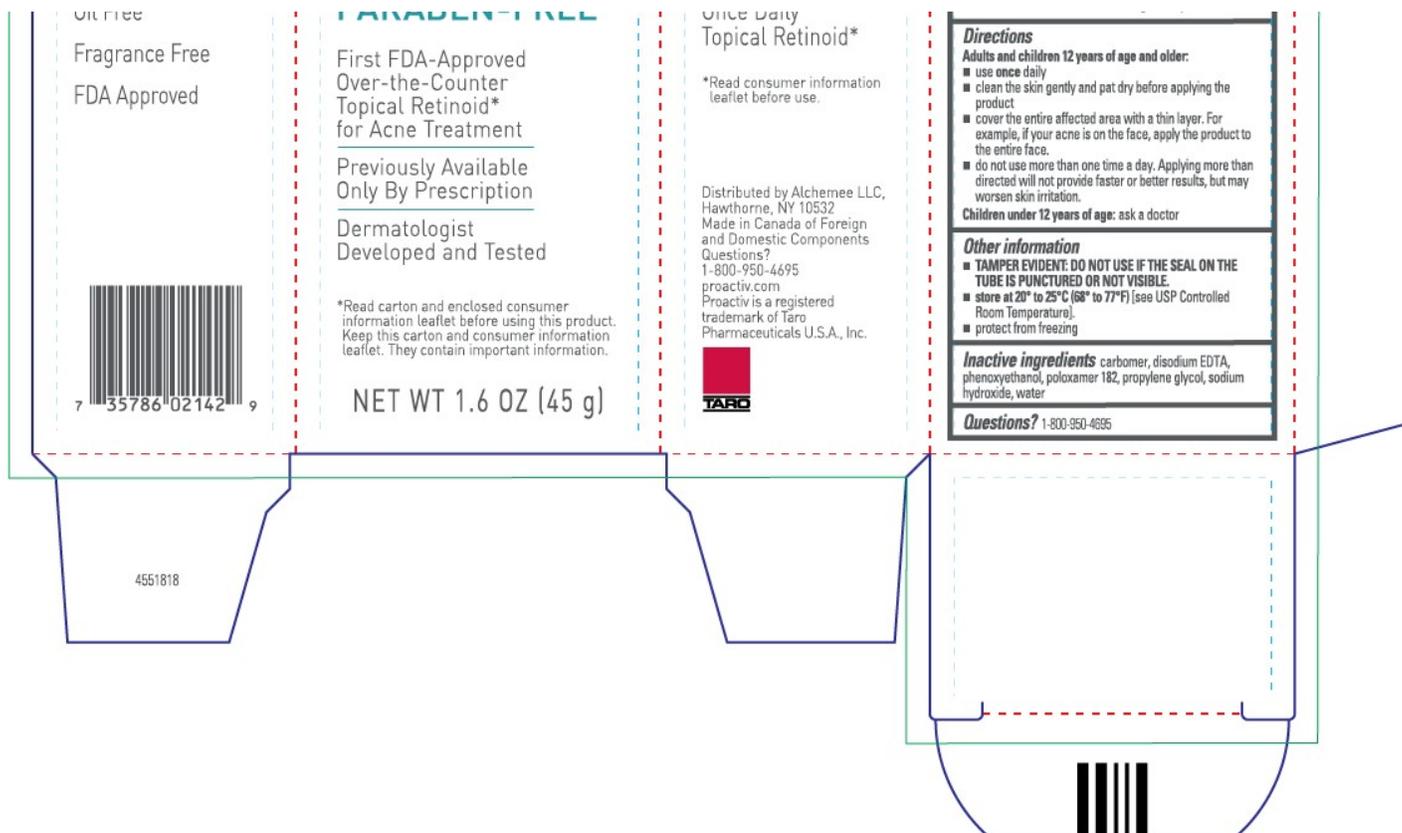
Previously Available
Only By Prescription

Dermatologist
Developed and Tested

*Read carton and enclosed consumer
information leaflet before using
this product. Keep this carton and
consumer information leaflet.
They contain important information.

NET WT 1.6 OZ (45 g)





PROACTIV MD ADAPALENE ACNE TREATMENT

adapalene gel

Product Information

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11410-958-45	1 in 1 BOX	11/16/2023	
1		45 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:11410-958-15	1 in 1 BOX	11/16/2023	
2		15 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
ANDA	ANDA215940	11/16/2023	

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

Revised: 11/2023

Alchemee, LLC