

**AVENE CLEANANCE ACNE MEDICATED CLEARING TREATMENT- benzoyl peroxide liquid  
Pierre Fabre USA Inc.**

*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.*

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**Avene Cleanance Acne Medicated Clearing Treatment**

**Drug Facts**

**Purpose**

Acne Treatment

**Active Ingredient**

BENZOYL PEROXIDE 5.5%

**Uses**

For the treatment of acne.

Dries and clears acne blemishes and allows skin to heal.

Helps keep skin clear of new acne blemishes

**Warnings**

**For external use only.**

**Do not use if you**

have very sensitive skin or are sensitive to benzoyl peroxide.

**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.

### **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**

clean the skin thoroughly before applying this product.

cover the entire affected area with a thin layer one to three times daily.

because excessive dry of the skin may occur, start with one application daily, then gradually increase to two or three times daily 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.

### **Inactive Ingredients**

Water (aqua), propanediol, dimethyl isosorbide, glycerin, 1,2-hexanediol, acrylamide/sodium acryloyldimethylurrate copolymer, isohexadecane, hydroxyacetophenone, hylocereus undatus fruit extract, polysorbate 80, polyglyceryl-2 isostearate, xanthan gum, sodium citrate, trisodium ethylenediamine disuccinate, citric acid, diethylhexyl sodium sulfosuccinate, carbomer, sodium hydroxide, hyaluronic acid, ethylhexylglycerin, morinda citrifolia extract, phenoxyethanol, dimethicone, sodium metabisulfite, peg-40 stearate, silica, sorbitan stearate, tocopherol

### **Questions**

1-866-41-AVENE (28363)

### **Packaging**

EAU THERMALE

AVENE

LABORATORIE DERMATOLOGIQUE

CLEANANCE

ACNE

MEDICATED CLEARING

TREATMENT



Ingredient Name	Strength	Strength
<b>BENZOYL PEROXIDE</b> (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	5.5 mg in 40 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)	
<b>SODIUM ACRYLOYLDIMETHYLTAURATE-ACRYLAMIDE COPOLYMER (1:1; 90000-150000 MPA.S)</b> (UNII: 5F4963KLHS)	
<b>HYLOCEREUS UNDATUS FRUIT</b> (UNII: WUG58TD53X)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>TRISODIUM ETHYLENEDIAMINE DISUCCINATE</b> (UNII: YA22H34H9Q)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>SODIUM METABISULFITE</b> (UNII: 4VON5FNS3C)	
<b>CARBOMER 1342</b> (UNII: 809Y72KV36)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>HYALURONIC ACID</b> (UNII: S270N0TRQY)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>PEG-40 STEARATE</b> (UNII: ECU18C66Q7)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)	
<b>MORINDA CITRIFOLIA FRUIT</b> (UNII: 7829X3G2X5)	
<b>PEG-20 SORBITAN STEARATE</b> (UNII: HD40WR33LC)	
<b>ISOHEXADECANE</b> (UNII: 918X1OUF1E)	
<b>POLYGLYCERYL-2 ISOSTEARATE</b> (UNII: 7B8OE71MQC)	
<b>DIHEXYL SODIUM SULFOSUCCINATE</b> (UNII: 7YY1T561V4)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64760-776-01	1 in 1 CARTON	05/30/2023	
1		5 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:64760-776-02	1 in 1 CARTON	05/30/2023	
2		40 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	05/30/2023	

**Labeler** - Pierre Fabre USA Inc. (117196928)

**Registrant** - Pierre Fabre USA Inc. (117196928)

Revised: 5/2023

Pierre Fabre USA Inc.