

## **DOUBLE FIGHT- salicylic acid and benzoyl peroxide**

### **Noon Aesthetics M.R. Ltd**

*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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## **Double Fight**

### **Drug Facts:**

### **Active Ingredients**

A - Therapeutic Hydrogel: Salicylic Acid 2%

B - Azelaic Cream: Benzoyl Peroxide 5%

### **Purpose**

Acne treatment

Use for the treatment 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 at a time.

### **Do not use**

- on broken skin
- on large areas of the skin

When using this product apply

- only to areas with acne
- rinse right away with water if it gets in eyes.

Stop use and ask a doctor if skin irritation occurs or gets worse.

If going outside, apply sunscreen after using this product. If irritation or sensitivity develop, stop use of both products and ask doctor.

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

### **Directions**

Sensitivity Test for a New User: Apply products sparingly to one or two small affected

areas during the first 3 days. If no discomfort occurs, follow the directions stated below.

Cleanse the skin thoroughly before applying this product. Cover the entire affected area with a thin layer of Therapeutic Hydrogel (A). After covering the affected area with Therapeutic Hydrogel, apply a thin layer of Azelaic Cream (B) 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 one a day or every other day.

### **Inactive Ingredients**

**Therapeutic Hydrogel (A)** Aqua, Lactic Acid, Propanediol, Dimethyl Sulfone, Strontium Chloride Hexahydrate, Polyacrylate Crosspolymer-6, Isononyl Isononanoate, Ethylhexyl Stearate, Citronellyl Methylcrotonate, Polysorbate 20, Phenoxyethanol, Cetyl Alcohol, Glyceryl Stearate, PEG-100 Stearate, Cetearyl Wheat Straw Glycosides, Cetearyl Alcohol, Cyclopentasiloxane, Dimethicone, Parfum, Caprylyl Glycol, T-Butyl Alcohol, Sodium Phytate, Xanthan Gum, Sodium Hydroxide, Alcohol, Limonene.

**Azelaic Cream (B)** Aqua, Azelaic Acid, Azeloglicina, Propylene Glycol, Propanediol, Dimethyl Sulfone, Strontium Chloride Hexahydrate, Alpha-Arbutin, Isononyl Isononanoate, Glycerin, Cyclopentasiloxane, Glyceryl Stearate, PEG-100 Stearate, Dimethyl Isosorbide, Sodium Hydroxide, Cetyl Palmitate, Phenoxyethanol, Xylitol, Dimethicone, Anhydroxylitol, Arachidyl Alcohol, Cetyl Alcohol, Behenyl Alcohol, Xylitylglucoside, Parfum, Citrus Limon Peel Oil, Arachidyl Glucoside, Caprylyl Glycol, Sodium Phytate, Propolis Extract, Glucose, Citric Acid, Sodium Benzoate, Potassium Sorbate, Alcohol.

### **Other information**

Protect this product from excessive heat and direct sun.

### **Questions or comments?**

**[www.noonaesthetics.com](http://www.noonaesthetics.com)** or call Toll Free **1-833-666-6246**

Developed and Dist. by  
NOON Aesthetics  
TLV, 62153

### **PRINCIPAL DISPLAY PANEL - Kit Carton**

noon™

Double Fight

with DermShield™

Advanced Therapeutic  
System for  
Acne Treatment

A

Therapeutic  
Hydrogel  
Lactic Acid 10%  
Salicylic Acid 2%

+

B  
BenzoAzelin  
Azelaic Acid 13%  
Azeloglicina 10%  
Benzoyl Peroxide 5%

PARACEUTICAL

50 gr / 1.76 Oz e



### Double Fight<sup>◇</sup>

#### Drug Facts:

#### Active Ingredients:

A - Therapeutic Hydrogel: Salicylic Acid 2%

B - BenzoAzelin: Benzoyl Peroxide 5%

Purpose: Acne treatment

Use for the treatment 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 at a time. Contains Strontium Chloride.

#### Do not use:

- on broken skin
- on large areas of the skin

When using this product apply:

- only to areas with acne
- rinse right away with water if it gets in eyes.

Stop use and ask a doctor if skin irritation occurs or gets worse.

If going outside, apply sunscreen after using this product. If irritation or sensitivity develop, stop use of both products and ask doctor.

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

#### Directions for Use:

Sensitivity Test for a New User: Apply products sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated below.

Cleanse the skin thoroughly before applying this product. Cover the entire affected area with a thin layer of Therapeutic Hydrogel [A]. After covering the affected area with Therapeutic Hydrogel, apply a thin layer of BenzoAzelin [B]. 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 one a day or every other day.

#### Inactive Ingredients:

**Therapeutic Hydrogel [A]:** Aqua, Lactic Acid, Propanediol, Dimethyl Sulfone, Strontium Chloride Hexahydrate, Polyacrylate Crosspolymer-6, Isononyl Isononanoate, Ethylhexyl Stearate, Citronellyl Methylcrotonate, Polysorbate 20, Phenoxyethanol, Cetyl Alcohol, Glycerol Stearate, PEG-100 Stearate, Cetearyl Wheat Straw Glycosides, Cetearyl Alcohol, Cyclopentasiloxane, Dimethicone, Fragrance, Caprylyl Glycol, T-Butyl Alcohol, Sodium Phytate, Xanthan Gum, Sodium Hydroxide, Alcohol, Limonene.

**BenzoAzelin [B]:** Aqua, Azelaic Acid, Potassium Azeloyl Diglycinate, Propylene Glycol, Propanediol, Dimethyl Sulfone, Strontium Chloride Hexahydrate, Isononyl Isononanoate, Glycerin, Cyclopentasiloxane, Glycerol Stearate, PEG-100 Stearate, Dimethyl Isosorbide, Sodium Hydroxide, Cetyl Palmitate, Phenoxyethanol, Xylitol, Dimethicone, Anhydroxylitol, Arachidyl Alcohol, Cetyl Alcohol, Behenyl Alcohol, Xylitylglucoside, Fragrance, Citrus Limon Peel Oil, Arachidyl Glucoside, Caprylyl Glycol, Sodium Phytate, Propolis Extract, Glucose, Citric Acid, Sodium Benzoate, Potassium Sorbate, Alcohol.

PARACEUTICAL

## Double Fight<sup>◇</sup>

with DermShield™

Advanced Therapeutic System for Acne Treatment

<b>A</b>	<b>+</b>	<b>B</b>
Therapeutic Hydrogel		BenzoAzelin
Lactic Acid 10%		Azelaic Acid 13%
Salicylic Acid 2%		Azeloglicina 10%
		Benzoyl Peroxide 5%

PARACEUTICAL

50 gr / 1.76 Oz e

Double Fight includes a combination of Therapeutic Hydrogel (Lactic Acid 10% and Salicylic Acid 2%) and BenzoAzelin (Azelaic Acid 13%, Azeloglicina 10% and Benzoyl Peroxide 5%) containing DermShield™. The DermShield™ technology allows the use of the product without causing irritation.

Double Fight is a therapeutic system used to treat acne. It reduces the growth of keratinocytes that block pore and sebaceous glands causing spots, as well as killing the bacteria that live on your skin that can be responsible for acne.

Other information - Protect this product from excessive heat and direct sun. Questions or comments? [www.noonaesthetics.com](http://www.noonaesthetics.com) or call Toll Free 1-833-666-6246

Developed and Dist. by NOON Aesthetics TLV, 42153, Made in Israel [www.noonaesthetics.com](http://www.noonaesthetics.com)



# DOUBLE FIGHT

salicylic acid and benzoyl peroxide kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:78863-1040
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78863-1040-2	1 in 1 BOX	01/05/2020	
1		1 in 1 BOTTLE, DISPENSING		

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, DISPENSING	25 g
Part 2	1 BOTTLE, DISPENSING	25 g

## Part 1 of 2

### SALICYLIC ACID

salicylic acid cream

## Product Information

<b>Route of Administration</b>	TOPICAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	0.5 g in 25 g

## Inactive Ingredients

Ingredient Name	Strength
Polysorbate 20 (UNII: 7T1F30V5YH)	
Propanediol (UNII: 5965N8W85T)	
Water (UNII: 059QF0K00R)	
PHYTATE SODIUM (UNII: 88496G1ERL)	
Dimethyl Sulfone (UNII: 9H4PO4Z4FT)	
Strontium Chloride Hexahydrate (UNII: O09USB7Z44)	
Xanthan Gum (UNII: TTV12P4NEE)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	

<b>LACTIC ACID, DL-</b> (UNII: 3B8D35Y7S4)
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)
<b>Cetearyl Wheat Straw Glycosides</b> (UNII: B44PS4T8IN)
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)
<b>Isononyl Isononanoate</b> (UNII: S4V5BS6GCX)
<b>OCTYL STEARATE</b> (UNII: 772Y4UFC8B)
<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>PEG-100 Stearate</b> (UNII: YD01N1999R)
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)
<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)
<b>Citronellyl Methylcrotonate</b> (UNII: K61O222P3D)
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		25 g in 1 BOTTLE, DISPENSING; Type 1: Convenience Kit of Co-Package		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	01/05/2020	

### Part 2 of 2

### BENZOYL PEROXIDE

benzoyl peroxide cream

### Product Information

**Route of Administration** TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Benzoyl Peroxide</b> (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	1.25 g in 25 g

### Inactive Ingredients

Ingredient Name	Strength
<b>Propanediol</b> (UNII: 5965N8W85T)	
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)	
<b>Azelaic Acid</b> (UNII: F2VW3D43YT)	
<b>Water</b> (UNII: 059QF0KO0R)	
<b>Sodium Hydroxide</b> (UNII: 55X04QC32I)	
<b>Alcohol</b> (UNII: 3K9958V90M)	
<b>ALPHA-ARBUTIN</b> (UNII: 72VUP07IT5)	
<b>Dimethyl Sulfone</b> (UNII: 9H4PO4Z4FT)	
<b>STRONTIUM CHLORIDE HEXAHYDRATE</b> (UNII: O09USB7Z44)	
<b>Glycerin</b> (UNII: PDC6A3C0OX)	
<b>Arachidyl Alcohol</b> (UNII: 1QR1QRA9BU)	
<b>Arachidyl Glucoside</b> (UNII: 6JWV35JOOJ)	
<b>ANHYDROUS DEXTROSE</b> (UNII: 5SL0G7R0OK)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>Cetyl Palmitate</b> (UNII: 5ZA2S6B08X)	
<b>Dimethyl Isosorbide</b> (UNII: SA6A6V432S)	
<b>Cetyl Alcohol</b> (UNII: 936JST6JCN)	
<b>ISONONYL ISONONANOATE</b> (UNII: S4V5BS6GCX)	
<b>Phenoxyethanol</b> (UNII: HIE492ZZ3T)	
<b>Caprylyl Glycol</b> (UNII: 00YIU5438U)	
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)	
<b>CYCLOMETHICONE 5</b> (UNII: 0THT5PCI0R)	
<b>Dimethicone</b> (UNII: 92RU3N3Y1O)	
<b>Xylitylglucoside</b> (UNII: 00IEZ166FB)	
<b>Anhydroxylitol</b> (UNII: 8XWR7NN42F)	
<b>Xylitol</b> (UNII: VCQ006KQ1E)	
<b>PROPOLIS WAX</b> (UNII: 6Y8XYV2NOF)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>Sodium Benzoate</b> (UNII: OJ245FE5EU)	
<b>Potassium Sorbate</b> (UNII: 1VPU26JZZ4)	
<b>PUMMELO</b> (UNII: ET1TN5W71X)	
<b>LEMON OIL, COLD PRESSED</b> (UNII: I9GRO824LL)	
<b>PHYTATE SODIUM</b> (UNII: 88496G1ERL)	
<b>POTASSIUM AZELOYL DIGLYCINATE</b> (UNII: N02RVN6NYP)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		25 g in 1 BOTTLE, DISPENSING; Type 1: Convenience Kit of Co-Package		

### Marketing Information

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OTC MONOGRAPH FINAL	part333D	01/05/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part333D	01/05/2020	

**Labeler** - Noon Aesthetics M.R. Ltd (600185560)

## Establishment

Name	Address	ID/FEI	Business Operations
NOON Aesthetics M.R Ltd		600185560	MANUFACTURE(78863-1040)

Revised: 1/2023

Noon Aesthetics M.R. Ltd