# DR SONG ACNE- benzoyl peroxide gel Secret By Nature LLC

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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**Dr Song Acne** 

## **ACTIVE INGREDIENT**

Active	Purpose
BENZOYL PEROXIDE	Acne Treatment

#### **INACTIVE INGREDIENT**

CARBOMER, EDETATE DISODIUM, GLYCERINE, PROPYLENE GLYCOL, SACCHARIDE ISOMERATE, SODIUM HYDROXIDE, WATER

## KEEP OUT OF REACH OF CHILDREN

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

#### INDICATIONS & USAGE

For the treatment of acne

#### WARNINGS

For external use only.

- 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.
- If going outside, apply sunscreen after using this product.
- Keep away from excessive heat or heat sources

## Do to use if you:

- Have very sensitive skin
- 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.

#### **DIRECTIONS**

• Clean the skin thoroughly before applying this product

- Cover the entire affected area with a thin layer one to three times daily Use about a quarter sized amount.
- 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 once a day or every other day.
- Other sun protection measures include limiting sun exposure and wearing protective clothing.

## **PURPOSE**

For the treatment of acne.

# Stop use and ask a doctor if:

Sensitivity develops or irritation becomes severe, stop us and ask a doctor.

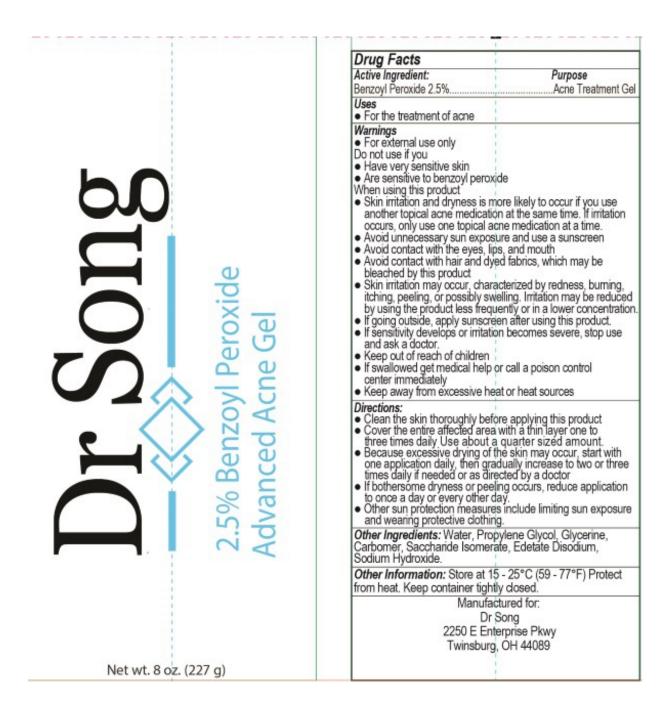
# Distributed By:

Dr Song, 2250 E Enterprise Pkwy TWINSBURG, OH, 44089

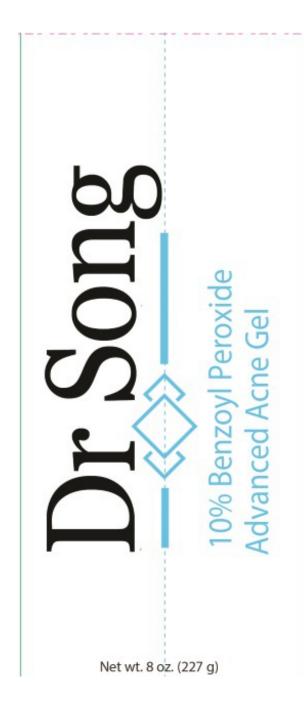
## Other Information:

Store: At Room Temperature 15° - 25°C (59°- 77°F). Protect from heat. Keep container tightly closed.

Dr Song Acne 2.5%



Dr Song Acne 10%



Drug Facts	}
Active Ingredient:	Purpose
Benzoyl Peroxide 10%	Acne Treatment Gel
Uses	1
<ul> <li>For the treatment of acne</li> </ul>	
Warnings	
<ul> <li>For external use only Do not use if you</li> </ul>	1
Have very sensitive skin	1
<ul> <li>Are sensitive to benzoyl perox</li> </ul>	dde
When using this product	
<ul> <li>Skin irritation and dryness is n another topical acne medication</li> </ul>	on at the same time. If irritation
<ul> <li>occurs, only use one topical a</li> <li>Avoid unnecessary sun expos</li> </ul>	che medication at a time.
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bleached by this product	
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ticning, peeling, or possibly sv	veiling, imitation may be reduced uently or in a lower concentratio
<ul> <li>If going outside, apply sunscreen</li> </ul>	en after using this product
<ul> <li>If sensitivity develops or irritati</li> </ul>	on becomes severe, stop use
and ask a doctor.	
<ul> <li>Keep out of reach of children</li> </ul>	1
<ul> <li>If swallowed get medical help</li> </ul>	or call a poison control
<ul> <li>Keep away from excessive he</li> </ul>	eat or heat sources
Directions:	out of ficul occioes
<ul> <li>Clean the skin thoroughly bef</li> </ul>	ore applying this product
<ul> <li>Cover the entire affected area</li> </ul>	a with a thin layer one to
three times daily Use about	a quarter sized amount.
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times daily if needed or as dir	adually increase to two or three
<ul> <li>If bothersome dryness or pee</li> </ul>	ling occurs, reduce application
to once a day or every other	day.
	es include limiting sun exposure
and wearing protective dothir	ng.
Other Ingredients: Water, Pro Carbomer, Sacchande Isomer	pylene Grycol, Grycenne,
Sodium Hydroxide.	ate, Edetate Disodium,
Other Information: Store at 1	5 - 25°C (50 - 77°E) Protect
from heat. Keep container tigh	fly doesd
	ctured for:
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	terprise Pkwy
i winsburg	, OH 44089

# DR SONG ACNE

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71174-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9 WZN9 A0 GM) (BENZOYL PEROXIDE - UNII:W9 WZN9 A0 GM)	BENZOYL PEROXIDE	25 mg in 1 g

# **Inactive Ingredients**

Ingredient Name	Strength
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
SO DIUM HYDRO XIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

	Packaging			
l	# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
	1 NDC:71174-100-01	227 g in 1 BOTTLE; Type 0: Not a Combination Product	12/0 1/20 15	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333D	12/01/2015		

# DR SONG ACNE

benzoyl peroxide gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71174-200	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
BENZO YL PERO XIDE (UNII: W9 WZN9 A0 GM) (BENZO YL PERO XIDE - UNII:W9 WZN9 A0 GM)	BENZOYL PEROXIDE	100 mg in 1 g		

Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)			
EDETATE DISO DIUM (UNII: 7FLD9 1C86K)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
SACCHARIDE ISOMERATE (UNII: W8K377W98I)			
SODIUM HYDROXIDE (UNII: 55X04QC32I)			
WATER (UNII: 059QF0KO0R)			

Pa	ckaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>

1 NDC:71174-200-01	227 g in 1 BOTTLE; Type 0: Not a Combination Product	12/0 1/20 15		
Marketing Information				
Marketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part333D	12/0 1/20 15		

# **Labeler** - Secret By Nature LLC (079571146)

Establishment			
Name	Address	ID/FEI	Business Operations
Pharmco Laboratories Inc		096270814	MANUFACTURE(71174-100, 71174-200)

Revised: 1/2017 Secret By Nature LLC