UTILIDERM ACNE CONTROL- sulfur,resorcinol gel
Sante Naturelle (A.G.) Ltee

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.

Utiliderm Acne Control Gel

Active Ingredients

Sulfur 4%

Resorcinol 2%

Purpose

acne medication

acne medication

Use

for the treatment of acne

Warnings

For external use only

Do not use on

■ broken skin ■ large areas of the skin

When using this product

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

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

Keep out of reach of children. If swallowed, get medical help or contact 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 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 information

■ keep tightly closed ■ keep away from heat

■ Report serious adverse reaction to:

c/o Report Reaction, LLC, P.O. Box 22,

Plainsboro, New Jersey 08536-0222

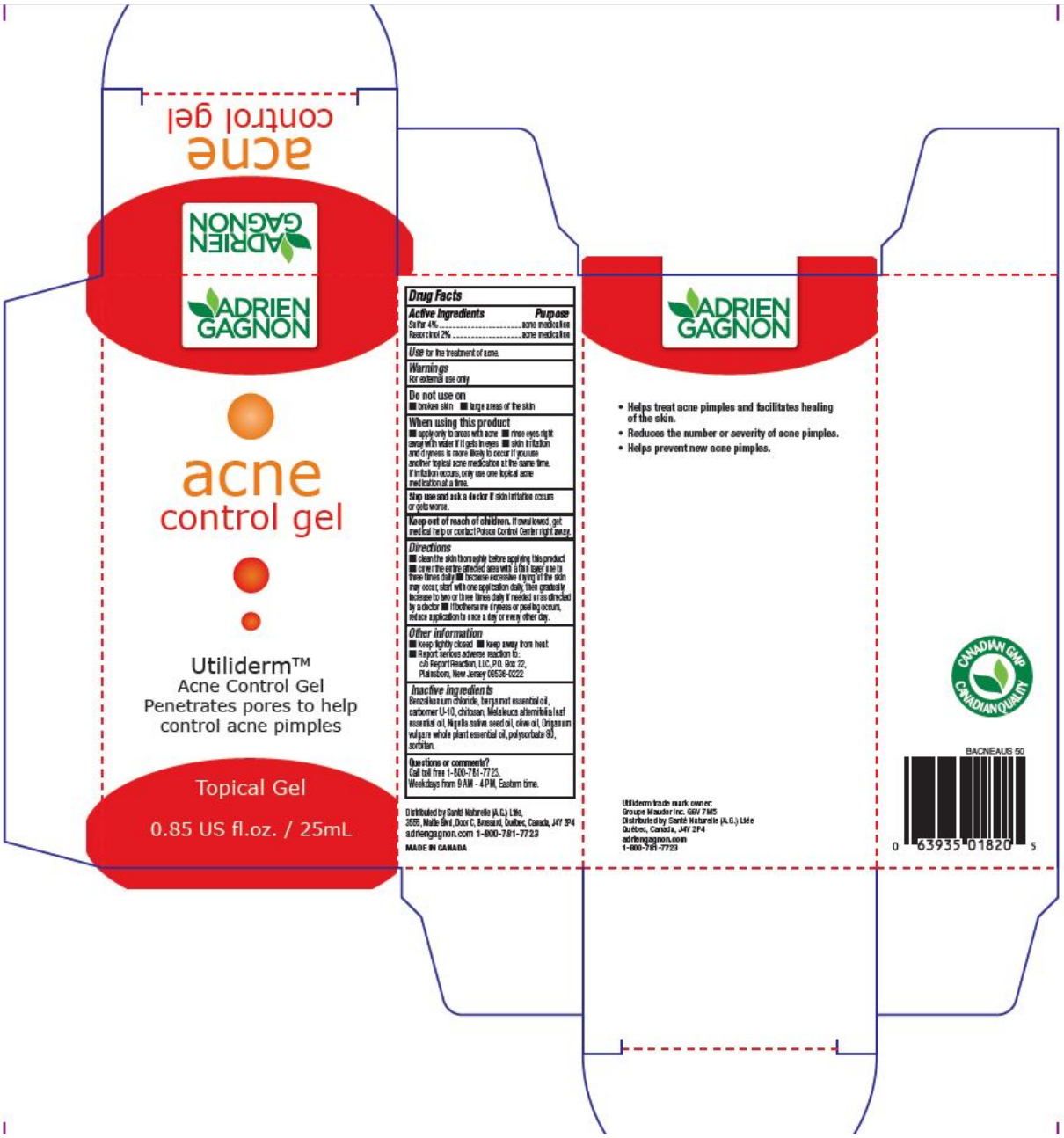
Inactive ingredients

Benzalkonium chloride, bergamot essential oil, carbomer U-10, chitosan, Melaleuca alternifolia leaf essential oil, Nigella sativa seed oil, olive oil, Origanum vulgare whole plant essential oil, polysorbate 80, sorbitan.

Questions or comments?

Call toll free 1-800-781-7723.

Weekdays from 9 AM - 4 PM, Eastern time.



UTILIDERM ACNE CONTROL

sulfur,resorcinol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71493-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	4 mg in 100 mL
RESORCINOL (UNII: YUL4LO94HK) (RESORCINOL - UNII:YUL4LO94HK)	RESORCINOL	2 mg in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BERGAMOT OIL (UNII: 39W1PKE3JI)	
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)	
NIGELLA SATIVA SEED OIL (UNII: CS4U38E731)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SORBITAN (UNII: 6O92ICV9RU)	
CHITOSAN MEDIUM MOLECULAR WEIGHT (200-400 MPA.S) (UNII: 5GV09YMO52)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
ORIGANUM VULGARE SUBSP. HIRTUM WHOLE (UNII: 38SNL0F81Z)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	

Product Characteristics			
Color	yellow (light)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71493-001-25	1 in 1 CARTON	04/02/2018	
1		25 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
OTC monograph final	part333D	04/02/2018	

Labeler - Sante Naturelle (A.G.) Ltee (207933979)

Registrant - Delta Pharma Inc (200161730)

Establishment

Name	Address	ID/FEI	Business Operations
Delta Pharma Inc.		200161730	manufacture(71493-001)

Revised: 3/2018 Sante Naturelle (A.G.) Ltee