NEOVA BREAKOUT CONTROL- salicylic acid swab
PhotoMedex, 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.

Neova Breakout Control - Drug Facts

Active Ingredients

Salicylic Acid 2%

Purpose

Acne Treatment

Uses

• For the treatment of acne. • Helps prevent new acne pimples, blackheads and whiteheads.

Warnings

For external use only

When using this product

Avoid contact with eyes. If contact occurs, flush thoroughly with water. Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor. Do not insert in ear canal.

Keep out of reach of children.

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

Directions

• Snap the tip at the color ring. • Allow formula to flow down to the opposite tip. • Apply formula with the saturated tip to affected area.

Other Information

Avoid storing at excessive heat.

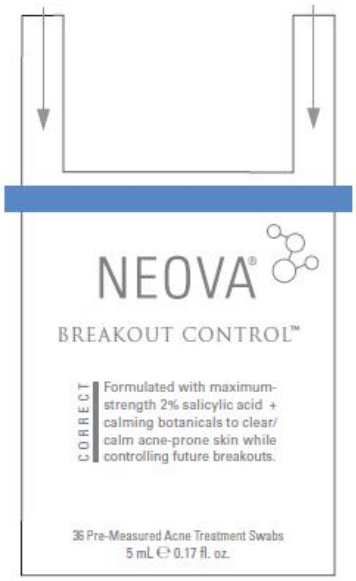
Inactive Ingredients

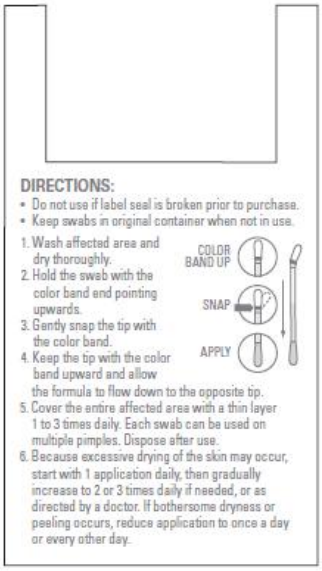
Allantoin, Hamamelis Virginiana (Witch Hazel) Water, Aloe Barbadensis Leaf Extract, Isoceteth-20, Methyl Gluceth-20, PEG-6,

Propylene Glycol, Sodium Hydroxide, Sodium PCA, Sorbitol, Tetrasodium EDTA, Water (Aqua).

Image of Box Label

BreakOutControlBoxLabel112611.jpg





NEOVA BREAKOUT CONTROL

salicylic acid swab

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62362-119
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Salicylic Acid (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	2 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Allantoin (UNII: 344S277G0Z)	
Hamamelis Virginiana Leaf Water (UNII: 8FP93ED6H2)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Isoceteth-20 (UNII: O020065R7Z)	
Methyl Gluceth-20 (UNII: J3QD0LD11P)	
Polyethylene Glycol 300 (UNII: 5655G9Y8AQ)	

Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Sodium Pyrrolidone Carboxylate (UNII: 469OTG57A2)	
Sorbitol (UNII: 506T60A25R)	
Edetate Sodium (UNII: MP1J8420LU)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62362-119-36	36 in 1 BOX		
1	NDC:62362-119-05	5 mL in 1 APPLICATOR		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358B	12/27/2011	

Labeler - PhotoMedex, Inc. (054503875)

Establishment

Name	Address	ID/FEI	Business Operations
PhotoMedex, Inc.		054503875	manufacture

Revised: 12/2011 PhotoMedex, Inc.