#### ACNE WIPES- salicylic acid swab JIANGSU TERRA MEDICAL TECHNOLOGY CO 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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#### **Active ingredient**

Sallcylic Acid 0.5%

#### **Purpose**

acne treatment

#### Use

for the treatment of acne.

#### Warnings

for external use only

ask a doctor or pharmacist before use if you are using other topical acne medications at the same time or immediately

over large areas of the body following use of this product.

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 contact with eyes, if contact occurs, flush thoroughly with water.

## Keep out of reach of children .if swallowed, get medical help or contact a Poison Control Center reght away.

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

#### Directions

use daily to get clear skin.

clean the skin thoroughly before applying this product.

cover the entire affected area 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.

throw away cloth(do not flush)

water ,cetearyl isononaneate,ceteareth-20,fregrance,cetearyl alcohol,glyceryl stearate,glycerin,ceteareth-12,cetyl palmitate,proplyene glycol,methjylparaben,disodium EDTA,propylparaben,2-bromo-2-nitropropane-1,3-Diol

# Acne Wipes

- Salicylic Acid Acne Treatment
  - Pre-Moistened Wipes

## MOISTURIZING AND CLEANSING **30** count 7.08 in. X 7.75 in. (17.9 cm x 19.6 cm)

#### Drug Facts

Active ingredient Salicylic Acid 0.5%

Purpose

Acne Treatment

#### Use for the treatment of acne.

Warnings For external use only.

Ask a doctor or pharmacist before use if you are using other topical acne medications at the same time or immediately following use of this product.

- 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 contact with eyes. If contact occurs, flush thoroughly with water Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

#### Drug Facts (continued)

#### Directions

- Directions

  use daily to get clear skin.

  clean the skin thoroughly before applying this product.

  cover the entire affected area 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.

  throw away cloth (do not flush).

#### Other information store at room temperature.

#### Inactive ingredients

Water, Cetearyl Isononanoate, Ceteareth-20, Fragrance, Cetearyl Alcohol, Glyceryl Stearate, Glycerin, Ceteareth-12, Cetyl Palmitate, Propylene Glycol, Methylparaben, Disodium EDTA, Propylparaben, 2-Bromo-2-Nitropropane-1,3-Diol

#### **ACNE WIPES**

salicylic acid swab

#### **Product Information**

HUMAN OTC DRUG Product Type Item Code (Source) NDC:69733-566

TOPICAL **Route of Administration** 

#### Active Ingredient/Active Moiety

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	Ingredient Name	Basis of Strength	Strength
	SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	5 mg in 1000 mg

Inactive Ingredients		
Ingredient Name	Strength	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
CETEARYL ISONONANOATE (UNII: P5001U99NI)		
CETEARETH-2 PHO SPHATE (UNII: 8NSU66JGZR)		
GLYCERIN (UNII: PDC6A3C0OX)		
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)		
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)		
CETEARETH-12 (UNII: 7V4MR24V5P)		
CETYL PALMITATE (UNII: 5ZA2S6B08X)		
METHYLPARABEN (UNII: A218 C7HI9 T)		
DISO DIUM EDTA-CO PPER (UNII: 6 V475AX06U)		
BRONOPOL (UNII: 6PU1E16C9W)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		

ı	Packaging					
ı	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date		
ı	1 NDC:69733-566-08	30 in 1 PACKAGE				
ı	1	0.623 mg in 1 POUCH; 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	09/30/2015		

### Labeler - JIANGSUTERRA MEDICALTECHNOLOGY COLTD (421340473)

Establishment				
Name	Address	ID/FEI	Business Operations	
JIANGSU TERRA MEDICAL TECHNOLOGY CO LTD		421340473	manufacture(69733-566)	

Revised: 9/2015 JIANGSU TERRA MEDICAL TECHNOLOGY CO LTD