# SALICYLIC ACID ACNE TREATMENT- salicylic acid soap Xtreme Tools International, 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.

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## Okay BODY SOAP BAR- SALICYLIC ACID ACNE TREATMENT

### **Drug Facts**

#### **Active Ingredient**

Salicylic Acid (2%)

#### **Purpose**

Acne Treatment

#### Use

For the treatment of acne.

#### Warning

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 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 right away.

#### **Directions**

Wet face. Work soap into a lather with hands and gently massage onto skin. Rinse.

## **Inactive Ingredients**

Sodium Palmate, Sodium Palm Kernelate, Sodium Cocoate, Water (Aqua), Glycerin, Cocos nucifera (Coconut)

Oil, Leptospermum Scoparium Branch/Leaf (Manuka) Oil, Limnanthes Alba (Meadowfoam) Seed Oil, Calendula Officinalis Flower Extract, Aloe Barbadensis Leaf Extract, Allantoin, Tocopheryl Acetate, Tetrasodium Etidronate, Sodium Chloride, Fragrance.

#### Questions or comments?

Call 1-305-622-7474 Mon-Fri 9 am-5 pm

#### **PACKAGE LABEL**

NDC 74553-012-01



## SALICYLIC ACID ACNE TREATMENT

salicylic acid soap

#### **Product Information Product Type** Item Code (Source) NDC:74553-012 HUMAN OTC DRUG **TOPICAL**

Active Ingredient/Active Moiety					
Ingredient Name	<b>Basis of Strength</b>	Strength			
Salicylic Acid (UNII: 0414P74LP7) (SALICYLIC ACID - UNII:0414P74LP7)	Salicylic Acid	2 g in 100 g			

Inactive Ingredients			
Ingredient Name	Strength		
SODIUM PALMATE (UNII: S0A6004K3Z)			
SODIUM PALM KERNELATE (UNII: 6H91L1NXTW)			
SODIUM COCOATE (UNII: R1TQH25F4I)			
WATER (UNII: 059QF0KO0R)			
GLYCERIN (UNII: PDC6A3C0OX)			
COCONUT OIL (UNII: Q9L0O73W7L)			
MANUKA OIL (UNII: M6QU9ZUH2X)			
MEADOWFOAM SEED OIL (UNII: 412ZHA4T4Y)			
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
ALLANTOIN (UNII: 344S277G0Z)			
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)			
ETIDRONATE TETRASODIUM (UNII: CZZ9T1T1X4)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	NDC:74553-012- 01	255 g in 1 BOX; Type 0: Not a Combination Product	09/11/2023	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	M006	09/11/2023		

## Labeler - Xtreme Tools International, Inc (125398904)

**Route of Administration** 

Xtreme Tools International, Inc Revised: 9/2023