INIXIAL PERFECTION MATT BALANCING CARE SALICYLIC ACID 2% ACNE TREATMENT- salicylic acid cream IXXI S.A.S.

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.

Inixial Perfection MATT BALANCING CARE Salicylic Acid 2% Acne Treatment Solution

Drug Facts

Active ingredients

Salicylic acid 2%

Purpose

Acne treatment solution

Uses

- For the treatment of acne.
- Dries and clears acne blemishes and allows skin to heal.
- Helps prevent new acne blemishes.

Warnings

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 acne medication at a time

Keep out of reach of children.

If swallowed, get medical help or contact a 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.

Sensitivity Test for a New User. Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.

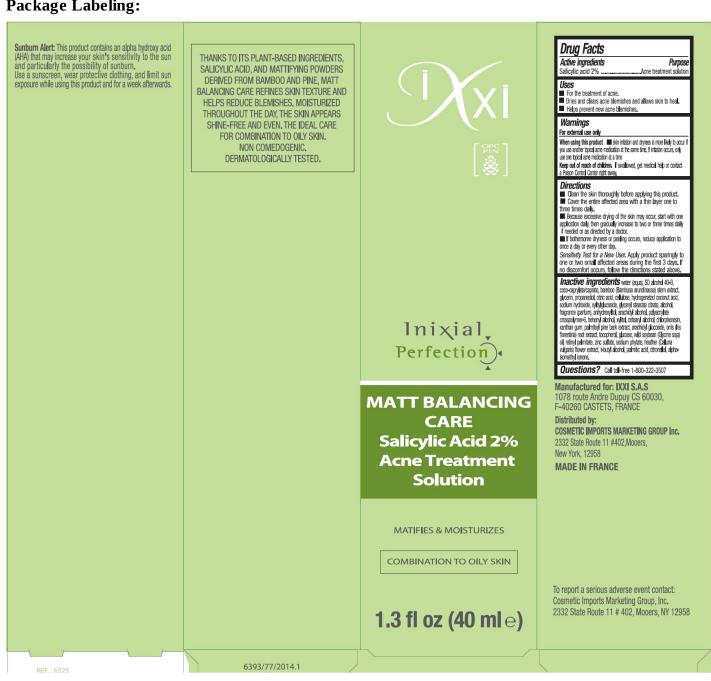
Inactive ingredients

water (aqua), SD alcohol 40-B, coco-caprylate/caprate, bamboo (bambusa arundinacea) stem extract, glycerin, propanediol, citric acid, cellulose, hydrogenated coconut acid, sodium hydroxide, xylitylglucoside, glyceryl stearate citrate, alcohol, fragrance (parfum), anhydroxylitol, arachidyl, polyacrylate crosspolymer-6, behenyl alcohol, xylitol, cetearyl alcohol, chlorphenesin, xanthan gum, palmitoyl pine bark extract, arachidyl glucoside, orris (Iris florentina) root extract, tocopherol, glucose, wild soybean (glycine soja) oil, retinyl palmitate, zinc sulfate, sodium phytate, heather (calluna vulgaris) flower extract, t-butyl alcohol, palmitic acid, citronellol, alphaisomethyl ionone.

Questions?

Call toll-free 1-800-322-3507

Package Labeling:



INIXIAL PERFECTION MATT BALANCING CARE SALICYLIC ACID 2% ACNE **TREATMENT**

salicylic acid cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70532-002	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
COCO-CAPRYLATE/CAPRATE (UNII: 8 D9 H4QU9 9 H)	
BAMBUSA BAMBOS STEM (UNII: NRA4497HC5)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPANEDIOL (UNII: 5965N8W85T)	
CITRIC ACID MO NO HYDRATE (UNII: 2968 PHW8 QP)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
XYLITYLGLUCO SIDE (UNII: O0 IEZ166FB)	
GLYCERYL STEARATE CITRATE (UNII: WH8T92A065)	
ALCOHOL (UNII: 3K9958V90M)	
ANHYDRO XYLITOL (UNII: 8 XWR7NN42F)	
DOCOSANOL (UNII: 9G10E216XY)	
XYLITOL (UNII: VCQ006KQ1E)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CHLORPHENESIN (UNII: 1670 DAL4SZ)	
XANTHAN GUM (UNII: TTV12P4NEE)	
ARACHIDYL GLUCOSIDE (UNII: 6JVW35JOOJ)	
IRIS GERMANICA VAR. FLORENTINA ROOT (UNII: M30 XO5X4XD)	
TOCOPHEROL (UNII: R0ZB2556P8)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9 XDZ35W2)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ZINC SULFATE (UNII: 89 DS0 H9 6 TB)	
PHYTATE SO DIUM (UNII: 88496G1ERL)	
TERT-BUTYL ALCOHOL (UNII: MD83SFE959)	
PALMITIC ACID (UNII: 2V16EO95H1)	
.BETACITRONELLOL, (R)- (UNII: P010UT964K)	
ISOMETHYLALPHAIONONE (UNII: 9XP4LC555B)	

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:70532-002-01	1 in 1 PACKAGE	04/03/2016		
1	40 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	04/01/2016			

Labeler - IXXI S.A.S. (263290505)

Revised: 4/2016 IXXI S.A.S.