

ATOA- rice bran extract cream
PROSAFEBIO

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ATOA
81745-301

purpose

Topical analgesic, Moisturizing, Skin protectant,Brightening

Use

Helps moistureize and relieve itching of dry skin.

Helps strengthen the weakened skin barrier.

Warnings

Do not use on damaged or broken skin.

Warnings

When using this product, do not use other than directed.

Warnings

Stop use and ask a doctor if irritation occurs.

Warnings

For external use only

Store at room temperature and avoid direct sunlight and high temperatures.

Warnings

Keep out of reach of children.

Directions

■Take an appropriate amount and gently spread it over.

■Reapply it frequently on the itchy area.

active ingredient

Rice Bran extract

Scutellaria baicalensis root extract

Opuntia humifusa stem extract

Sophora flavescens root extract

Angelica gigas root extract

Panax ginseng root extract

Inactive Ingredients

Purified water, Rice bran oil, Camellia Japonica Seed Oil, Sunflower seed oil, Glycerin, Butylene glycol, Simmondsia chinensis seed oil, Olive oil, Aloe baradensis leaf extract, Glyceryl caprylate, Centella Asiatica extract, Astragalus membranaceus root extract, Caprylyl glycol, Lavender oil, Sorbitan olivate, Xanthan gum, Ethylhexylglycerin, 1,2-Hexanediol, Disodium EDTA

Other information

Best before: 3 months after opening

Expiration date: indicated separately

Store at room temperature.

Question? Comments?

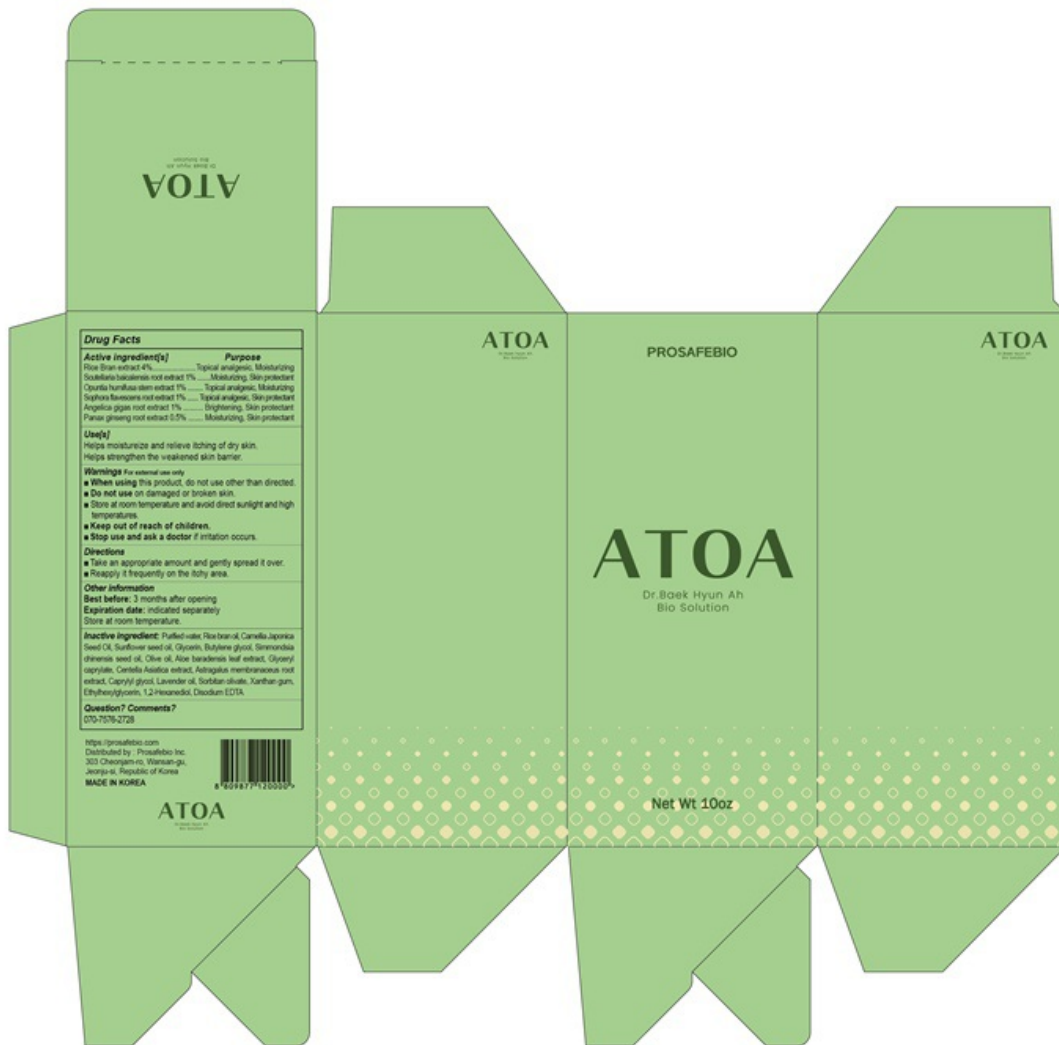
070-7576-2728

<https://prosafebio.com>

ATOA

LABEL

81745-301



ATOA

rice bran extract cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81745-301
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RICE BRAN (UNII: P600E12IC) (RICE BRAN (UNII: P600E12IC))	RICE BRAN	4 g

RICE BRAN (UNII: R0UQEF13IC) (RICE BRAN - UNII:R0UQEF13IC)	RICE BRAN	in 100 mL
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K) (SOPHORA FLAVESCENS ROOT - UNII:IYR6K8KQ5K)	SOPHORA FLAVESCENS ROOT	1 g in 100 mL
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S) (SCUTELLARIA BAICALENSIS ROOT - UNII:7J95K7ID2S)	SCUTELLARIA BAICALENSIS ROOT	1 g in 100 mL
OPUNTIA HUMIFUSA WHOLE (UNII: 6E9O5V4SS5) (OPUNTIA HUMIFUSA WHOLE - UNII:6E9O5V4SS5)	OPUNTIA HUMIFUSA WHOLE	1 g in 100 mL
ANGELICA GIGAS ROOT (UNII: 32766B2FHX) (ANGELICA GIGAS ROOT - UNII:32766B2FHX)	ANGELICA GIGAS ROOT	1 g in 100 mL
ASIAN GINSENG (UNII: CUQ3A77YXI) (ASIAN GINSENG - UNII:CUQ3A77YXI)	ASIAN GINSENG	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CAMELLIA JAPONICA SEED OIL (UNII: U37N0S910T)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASTRAGALUS PROPINQUUS ROOT POLYSACCHARIDES (UNII: 71WW2LNL50)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
GLYCERYL CAPRATE (UNII: 197M6VFC1W)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
SIMMONDSIA CHINENSIS SEED (UNII: D24K2Q1F6H)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
RICE BRAN OIL (UNII: LZ06K1506A)	
WATER (UNII: 059QF0KO0R)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81745-301-01	300 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/07/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/07/2022	

Registrant - PROSAFEBIO (695501710)**Establishment**

Name	Address	ID/FEI	Business Operations
PROSAFEBIO		695501710	manufacture(81745-301)

Revised: 10/2022

PROSAFEBIO