ARTRA SKIN TONE FOR OILY SKIN- hydroquinone, homosalate, oxybenzone cream J. Strickland & Co.

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.

Artra Skin Tone Cream for Oily Skin

Active Ingredients

Hydroquinone, 7.5%

Homosalate, 2%

Oxybenzone, 2.5%

Purpose

Sunscreen

Skin Lightener

Sunscreen

Uses:

Gradually fades skin discolorations such as

- age spots
- freckles
- Liver spots
- dark areas that can occur while using oral contraceptives

Warnings:

For external use only

Do not use

- to prevent sunburn
- if product is tan or brown
- on inflamed or broken skin

When using this product

- mild irritation may occur
- avoid contact with eyes. if contact occurs, rinse with water.
- avoid unnecessary sun exposure and use a sunscreen or protective clothing

Stop use and consult a doctor if

- a gradual blue-black darking of the skin occurs
- irritation becomes severe
- no improvement is seen after 3 months

If pregnant or breast feeding

consult a health professional before use.

Keep out of reach of children

In case of accidental ingestion, get medical help or contact a poison control center.

Directions

- If skin is sensitive, test on a small area inside elbow overnight before use.
- Adults and Children 12 years and older: apply as a thin layer to affected area twice daily or as directed by a doctor.
- Children under 12 years of age: ask a doctor before use.

Inactive Ingredients

water, glyceryl stearate, myristyl myristate, PEG-100 stearate, magnesium aluminum silicate, cetyl alcohol, dimenthicone, xanthan gum, stearic acid, palmitic acid, sodium sulfite, sodium lauryl sulfate, fragrance, citric acid, carathamus tinctorius (safflower) seed oil, ascorbic acid, methylparaben, tocopheryl acetate, aloe barbadensis leaf extract.

Package Labeling



ARTRA SKIN TONE FOR OILY SKIN

hydroquinone, homosalate, oxybenzone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12022-000
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
HYDRO Q UINO NE (UNII: XV74C1N1AE) (HYDRO QUINO NE - UNII: XV74C1N1AE)	HYDROQUINONE	75 mg in 1 g

	HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	20 mg in 1 g
ı	OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	25 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0KO0R)			
GLYCERYL MONOSTEARATE (UNII: 230 O U9 XXE4)			
MYRISTYL MYRISTATE (UNII: 4042ZC00DY)			
PEG-100 STEARATE (UNII: YD0 1N1999R)			
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
DIMETHICO NE (UNII: 92RU3N3Y1O)			
XANTHAN GUM (UNII: TTV12P4NEE)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
PALMITIC ACID (UNII: 2V16EO95H1)			
SODIUM SULFITE (UNII: VTK01UQK3G)			
SO DIUM LAURYL SULFATE (UNII: 368 GB5141J)			
CITRIC ACID MO NO HYDRATE (UNII: 2968PHW8QP)			
ASCORBIC ACID (UNII: PQ6CK8PD0R)			
METHYLPARABEN (UNII: A218 C7H19 T)			
ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12022-000-00	1 in 1 CARTON	12/0 1/19 9 0	
1		57 g 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 not final	part358A	12/01/1990		

Labeler - J. Strickland & Co. (007023112)

Registrant - J. Strickland & Co. (007023112)

Establishment				
Name	Address	ID/FEI	Business Operations	
J. Strickland & Co.		007023112	manufacture(12022-000), pack(12022-000), label(12022-000)	

Revised: 1/2018 J. Strickland & Co.