SSEUG SSAGCREAM- xanthium strumarium fruit extract, canavalia gladiata extract cream S-ONE PHARMACEUTICAL INC

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.

74721-0100 SSEUG SSAG CREAM

Active ingredients

- Xanthium Strumarium Fruit Extract 10%(w/w)
- Canavalia Gladiata Extract 5%(w/w)

Purpose

Hand & Feet skin softening product

Use

It is a cream made by using xanthium strumarium fruit extract as the main ingredient and helps various skin problems.

Warnings

For external use only.

Make sure to close the cap after use.

Do not use

Do not use it if you have red spots, swelling, itching or irritation on skin during use

Do not use it if the area of application is abnormal due to direct sunlight.

Do not use this product on skin with wounds or bleeding.

Do not use eat this product, and if ingested, consult a specialist immediately.

Do not use it for anything other than its purpose.

If it gets in your eyes, rinse it with water immediately.

Keep out of the reach of children.

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Other Information

Avoid hot or cold places or in direct sunlight.

Directions

- 1) Wash your hands and feet with clean foot soap and use a towel and dryer to completely remove moisture
- 2) After applying this product thickly to the nails or toenails you want to use, attach it using a gauze or a disposable band to prevent the cream from being lost to the outside.

Inactive ingredients

Water, Petrolatum, Olea Europaea (Olive) Fruit Oil, Propylene Glycol, Cetyl Alcohol, Polysorbate 60,

Beeswax, Aloe Arborescens Leaf Extract, Glyceryl Stearate, Butyrospermum Parkii (Shea)Butter,

Hyaluronic Acid, Citric Acid, Polylysine, Glycerin

Package Label





SSEUG SSAGCREAM

xanthium strumarium fruit extract, canavalia gladiata extract cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74721-0100	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CANAVALIA GLADIATA WHOLE (UNII: 9PHQ0141AL) (CANAVALIA GLADIATA WHOLE - UNII:9PHQ0141AL)	CANAVALIA GLADIATA WHOLE	5 g in 100 mL	
XANTHIUM STRUMARIUM FRUIT (UNII: TN770YC17C) (XANTHIUM STRUMARIUM	XANTHIUM	10 g	

Inactive Ingredients			
Ingredient Name	Strength		
PETROLATUM (UNII: 4T6H12BN9U)			
CETYL ALCOHOL (UNII: 936JST6JCN)			
SHEA BUTTER (UNII: K49155WL9Y)			
GLYCERIN (UNII: PDC6A3C0OX)			
OLIVE OIL (UNII: 6UYK2W1W1E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
POLYSORBATE 60 (UNII: CAL22UVI4M)			
YELLOW WAX (UNII: 2ZA36H0S2V)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
HYALURONIC ACID (UNII: S270N0TRQY)			
WATER (UNII: 059QF0KO0R)			
POLY-L-LYSINE (30000-70000 MW) (UNII: 0A1V8JTU2M)			

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:74721- 0100-1	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
unapproved drug other		07/22/2022	

Labeler - S-ONE PHARMACEUTICAL INC (694626932)

Registrant - S-ONE PHARMACEUTICAL INC (694626932)

Establishment				
Name	Address	ID/FEI	Business Operations	
S-ONE PHARMACEUTICAL INC		694626932	manufacture(74721-0100)	

Revised: 1/2023 S-ONE PHARMACEUTICAL INC