

**TROUVAILLE SUNSCREEN BROAD SPECTRUM SPF 30 UVA/UVB- trouvaille
sunscreen broad spectrum spf 30 uva/uvb cream
Monaesi Phytoceuticals**

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.

I am trying to list sunscreen.

Active Ingredient(s)

Zinc oxide

Purpose

sunscreen

Use

helps prevent sunburn"

Warnings

Do not use on damaged or broken skin"

"When using this product keep out of eyes. Rinse with water to remove."

"Stop use and ask a doctor if rash occurs"

For sunscreen drug products that do not pass the Broad Spectrum Test or that have SPF values less than 15, the first statement under Warnings must be:

"Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging."

Do not use

"Do not use on damaged or broken skin"

When using this product keep out of eyes. Rinse with water to remove

"Stop use and ask a doctor if rash occurs

Other information

"protect the product in this container from excessive heat and direct sun

Inactive ingredients

Water, Coco-Caprylate/Caprate, Butyloctyl Salicylate, Caprylic/Capric Triglyceride, Glycerin, Cetearyl Alcohol, Jojoba Esters, Sylibum Marianum Ethyl Ether, Gum Arabica, Cetyl Palmitate, Sorbitan Palmitate, Sorbitan Olivatate, Inulin, Tetrahexyldecyl Ascorbate, Crocus Chrysanthus Bulb Extract, Hedychium Coronarium Root Extract, Fructooligosaccharides, Punica Granatum Fruit Extract, Beta Vulgaris (beet) Root Extract, Ficus Carica (fig) Fruit Extract, Glyceryl Stearate, Tocopherol, Morus Alba Fruit Extract, Ginkgo Biloba Nut Extract, Potassium Lactate, Lactic Acid, Triethoxycaprylsilane, Polyhydroxystearate Acid, Sclerotium Gum, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Pullulan, Lecithin, Silica, Tetrasodium Glutamate Diacetate, Caprylhydroxamic Acid, Glyceryl Caprylate, Nitrotriacetic Acid Trisodium Salt, Propanediol, Polysorbate-60, Sorbitan Isostearate

Package Label - Principal Display Panel

39.5*39.5*128mm-60ml SPF-30 tube

			
<p>Drug Facts</p> <p>Active Ingredients Purpose Zinc Oxide 20%.....Sunscreen</p> <p>Uses</p> <ul style="list-style-type: none"> ■ helps prevent sunburn ■ if used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun <p>Warnings</p> <p>Do not use on damaged or broken skin</p> <p>When using this product keep out of eyes. Rinse with water to remove.</p> <p>Stop use and ask a doctor if rash occurs</p> <p>Directions</p> <ul style="list-style-type: none"> ■ apply generously and evenly 15 minutes before sun exposure ■ children under 6 months of age: Ask a doctor ■ Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: 	<p>Drug Facts (Continued)</p> <ul style="list-style-type: none"> ■ limit time in the sun, especially from 10 a.m. - 2 p.m. ■ reapply at least every 2 hours ■ use a water-resistant sunscreen if swimming or sweating <p>Other Ingredients</p> <p>Water, Coco-Caprylate/Caprate, Butyloctyl Salicylate, Capryl/Capric Triglyceride, Glycerin, Cetearyl Alcohol, Jojoba Esters, Glyburide, Glyburide Ethyl Ether, Gum Arabic, Cetyl Palmitate, Sorbitan Palmitate, Sorbitan Olivale, Inulin, Tetrahexyldecyl Ascorbate, Crocus Chrysanthus Bulb Extract, Hedychium Coronarium Root Extract, Fructooligosaccharides, Punica Granatum Fruit Extract, Beta Vulgaris (beet) Root Extract, Ficus Carica (fig) Fruit Extract, Glyceryl Stearate, Tocopherol, Morus Alba Fruit Extract, Ginkgo Biloba Nut Extract, Potassium Lactate, Lactic Acid, Triethoxycaprylylsilane, Polyhydroxystearate Acid, Sclerotium Gum, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Povidone, Lecithin, Silica, Tetrasodium Glutamate Diacetate, Caprylhydroxamic Acid, Glyceryl Caprylate, Nitrotriacetic Acid Trisodium Salt, Propanediol, Polysorbate-60, Sorbitan Isostearate.</p> <p>Other Information</p> <ul style="list-style-type: none"> ■ protect the product in this container from excessive heat and direct sun <p>Questions? call 800-737-5550 or www.monaesiskincare.com</p>	 <p>MONAESI SKINCARE</p> <p>Trouvaille Age Inclusive, Lifestyle Inclusive Renew your youthful look</p> <p>Sunscreen Broad Spectrum SPF 30 UVA/UVB</p> <p>Skin safe + + Moisturize + Bright + Firm + Supple + Smooth + Resurface</p> <p>Collagen, Elastin supporting ingredients + Squalane + Jojoba + Prebiotics + Anti Pollution + Antioxidants- Vitamins E, C + Blue light defense</p> <p>Net Wt 2.1 Oz / 60 g</p>	<p>CLEAN BEAUTY</p>  <p>Distributed by Monaesi Phytoceuticals, Texas, 75033 Made in USA</p>
			

NDC: 82285-020-01

Please see the attached image

Sunscreen

Broadspectrum

SPF 30

TROUVAILLE SUNSCREEN BROAD SPECTRUM SPF 30 UVA/UVB

trouvaille sunscreen broad spectrum spf 30 uva/uvb cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82285-120
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	7 mg in 100 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82285-120-01	20 in 1 BOX	05/15/2022	
1		20 mg 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	part352	05/15/2022	

Labeler - Monaesi Phytoceuticals (117831373)**Registrant** - Monaesi Phytoceuticals (117831373)**Establishment**

Name	Address	ID/FEI	Business Operations
NATURAL TECHNOLOGY LLC		618561906	manufacture(82285-120)