

TENACIOUS ERGODYNE- spf 50 sunscreen lotion lotion
Tenacious Holdings, Inc.

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.

Tenacious Ergodyne SPF 50 Sunscreen Lotion

Active ingredients

Avobenzone 3.0%, Homosalate 10.0%, Octocrylene 6.0%

Purpose

Sunscreen

Uses

- 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

Warnings

For external use only

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.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure

- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- 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:
 - limit time in the sun, especially from 10 a.m.-2 p.m.
 - wear long-sleeved shirts, pants, hats, and sunglasses

Other information

- protect the product in this container from excessive heat and direct sun
- may stain or damage some fabrics/materials or surfaces

Inactive ingredients

water, cetearyl alcohol, stearyl alcohol, glycerin, acrylates/C12-22 alkyl methacrylate crosspolymer, cetyl alcohol, carbomer, ceteth-10 phosphate, dicetyl phosphate, cocoglucoside, xanthan gum, disodium EDTA, methyl dihydroabietate, lauryl PEG-8 dimethicone, phenylisopropyl dimethicone, polyglyceryl-3 stearate/isostearate/dimer dilinoleate crosspolymer, sodium ascorbyl phosphate, tocopheryl acetate, aloe barbadensis leaf juice, phenoxyethanol, triethanolamine, propylene glycol, hydroxyacetophenone.

Tenacious Ergodyne SPF 50 Lotion

8 FL OZ (237mL)

NDC 73620-001-11



Tenacious Ergodyne SPF 50 Lotion
 1.5 OZ (44mL)
 NDC 73620-001-49



KREW'D™

SUNSCREEN LOTION
FULL THROTTLE PROTECTION

THE NØ BS SPF™
NO STINK. NO DRIP. NO BULL.
DERMATOLOGIST TESTED
WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 50
50
UVA/UVB PROTECTION
1.5 FL. OZ (44mL)

PEEL
HERE 

KREW'D™

Sunscreen formulated and tested to withstand your daily grind. Plus, it's free of parabens and phthalates; is reef-safe; has a ZERO tolerance fragrance policy; and is hypoallergenic (for you sensitive types).

100% full-throttle protection - not available at a beauty counter near you.

ergodyne®

INTERGALACTIC HEADQUARTERS

44° 38' 18.37" N 93° 08' 12.88" W ALT. 834 FT.
1021 BANDAIA BOULEVARD EAST
SUITE 220 // SAINT PAUL, MN 55108
TOLL-FREE 800 225 8238 // INT'L +1 858 842 8888 // ERGODYNE.COM

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W30099A

Drug Facts

Active Ingredients

Avobenzone 3.0%
Homosalate 10.0%
Octocrylene 8.0%

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HINGE AREA

HINGE AREA

Drug Facts (continued)

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Tenacious Ergodyne SPF 50 Lotion

32 FL OZ (946mL)

NDC 73620-001-72

Sunscreen formulated and tested to withstand your daily grind. Plus, it's free of parabens and phthalates; is reef-safe; has a ZERO tolerance fragrance policy; and is hypoallergenic (for you sensitive types).

100% full-throttle protection – not available at a beauty counter near you.

THE NO BS SPF
NO STINK. NO DRIP. NO BULL.
DERMATOLOGIST TESTED
WATER RESISTANT (80 MINUTES)

BROAD SPECTRUM SPF 50
50
UVA/UVB PROTECTION
32 FL OZ (946mL)

ergodyne
INTERGALACTIC HEADQUARTERS
44" 50" 80.31" 4" 83" 50" 52.88" 4" 42.1" 834 FT.
100% PARABEN FREE FRAGRANCE FREE
DATE 2/22 // SAINT PAUL, MN 55108
TEL: 651.842.8222 // FAX: 651.842.8889 // ERGODYNE.COM
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Drug Facts

Active Ingredients	Purpose
Avobenzone 3.0% Homosalate 10.0% Octocrylene 6.0%	Sunscreen

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TENACIOUS ERGODYNE

spf 50 sunscreen lotion lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73620-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	30 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	100 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	60 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
BUTYL ACRYLATE/C16-C20 ALKYL METHACRYLATE/METHACRYLIC ACID/METHYL METHACRYLATE COPOLYMER (UNII: 7K68DGG29P)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)	
CETETH-10 PHOSPHATE (UNII: 4E05O5N49G)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5WN99N)	
COCO GLUCOSIDE (UNII: ICS790225B)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
METHYL DIHYDROABIETATE (UNII: 7666FJ0J9F)	
SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TROLAMINE (UNII: 9O3K93S3TK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73620-001-11	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/13/2020	
2	NDC:73620-001-49	44 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/13/2020	
3	NDC:73620-001-72	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/13/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	02/13/2020	

Labeler - Tenacious Holdings, Inc. (108665142)