

**THE INDIGO CALMING- colloidal oatmeal cream
TATCHA 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.

TATCHA® THE INDIGO CALMING CREAM

Drug Facts

Active Ingredient

Colloidal Oatmeal 2%

Purpose

Skin Protectant

Uses

Temporarily protects and helps relieve minor skin irritation and itching due to: • rashes • eczema

Warnings

For external use only. When using this product • do not get into eyes

Stop use and ask a doctor if: • condition worsens • symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply as needed.

Inactive Ingredients

Water/Aqua, Squalane, Dimethicone, Propanediol, Glycerin, Diisostearyl malate, Oryza Sativa (Rice) Bran Wax, Behenyl Alcohol, Beheneth-20, Sorbitan Tristearate, Bis-diglyceryl Polyacyladipate-2, Inositol, Saccharomyces/Rice Ferment Filtrate, Camellia Sinensis Leaf Extract, Cladosiphon Okamuranus Extract, Indigofera Tinctoria Leaf Extract, Polygonum Tinctorium Leaf/Stem Extract, Avena Sativa (Oat) Kernel Extract, Sophora Japonica Flower Extract, Oryza Sativa (Rice) Germ Oil, Cocos Nucifera (Coconut) Oil, Sericin, Tetrasodium Tetracarboxymethyl Naringeninhalcone,

Caprylyl/Capryl Glucoside, Sorbitan Isostearate, Sodium Hyaluronate, Trihydroxystearin, Dimethicone/Vinyl dimethicone Crosspolymer, Ethylhexylglycerin, Butylene Glycol, Sodium Dilauramidoglutamide Lysine, Ethylhexyl Palmitate, Sodium Acrylate/Acryloyldimethyltaurate/Dimethylacrylamide Crosspolymer, Phenoxyethanol, Titanium Dioxide (CI 77891), Tin Oxide (CI 77861), Mica (CI 77019)

Questions?

Call toll-free (877) 322-8633

soothing skin protectant

Reveal calm, smooth skin with our rich, fragrance-free moisturizer. This treatment contains Japanese indigo and delivers therapeutic colloidal oatmeal to provide soothing relief of redness and itchiness.

FORMULATED IN JAPAN
MADE IN USA

DIST. TATCHA LLC
SAN FRANCISCO, CA 94123 USA
UK: DELPHIC HSE GU14 7NA
NL: 104 SCHIPHOL, 1118CN
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TATCHA.COM

BEAUTIFUL FACES, BEAUTIFUL FUTURES

Your purchase supports education equality

www.tatcha.com/giving-back

Packaging

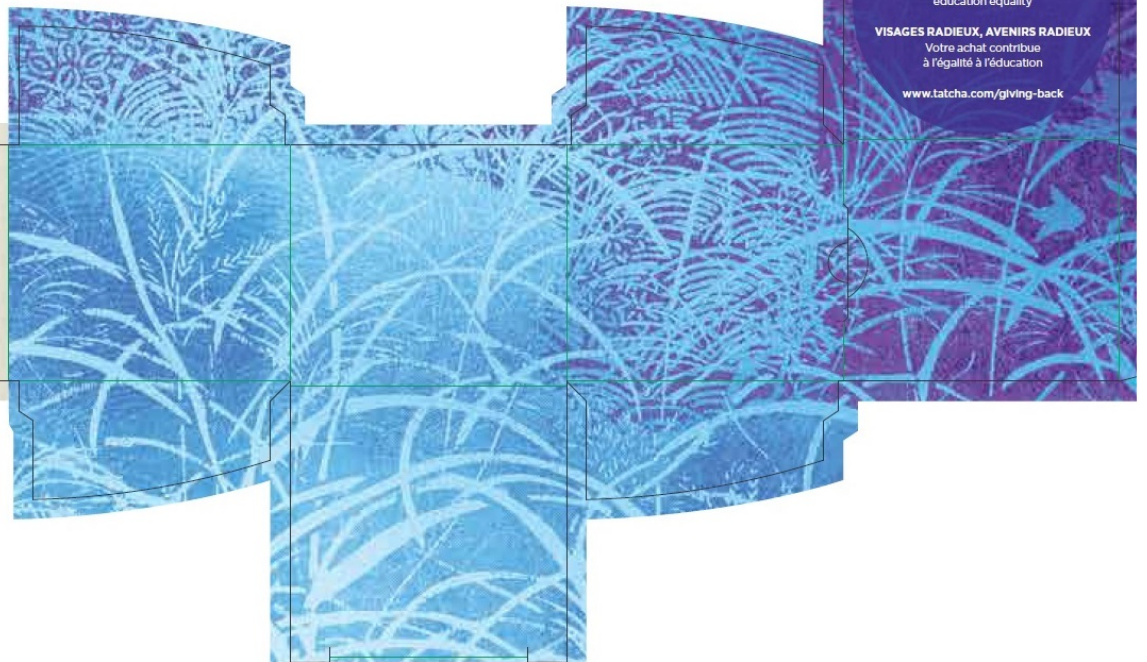
PACKAGE - 10 mL



Drug Facts (cont'd)

Inactive Ingredients (cont'd)
GERM OIL, COCOS NUCIFERA (COCONUT) OIL, SERICIN, TETRA SODIUM TETRACARBOXYMETHYLNARINGENINCHALONE, CAPRYLYL/CAPRYL GLUCOSIDE, SORBITAN ISOSTEARATE, SODIUM HYALURONATE, TRIHYDROXY STEARIN, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, ETHYLHEXYL GLYCERIN, BUTYLENE GLYCOL, SODIUM DILAURAMIDOGlutAMIDE LYSINE, ETHYLHEXYL PALMITATE, SODIUM ACRYLATE/ACRYLOYLDIMETHYL ACRYLATE/DIMETHYLACRYLAMIDE CROSSPOLYMER, PHENOXYETHANOL, TITANIUM DIOXIDE (CI 77891), TIN OXIDE (CI 7786), MICA (CI 77019)

Questions? Call toll-free (877) 322-8633



PACKAGE - 50 mL



THE INDIGO CALMING
colloidal oatmeal cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69417-140
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SQUALANE (UNII: GW89575KF9)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
PROPANEDIOL (UNII: 5965N8W85T)	

GLYCERIN (UNII: PDC6A3C0OX)
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)
RICE BRAN (UNII: R60QEP13IC)
BEHENETH-20 (UNII: BJ4GP2IFLN)
SORBITAN TRISTEARATE (UNII: 6LUM696811)
BIS-DIGLYCERYL POLYACYLADIPATE-2 (UNII: 6L246LAM9T)
INOSITOL (UNII: 4L6452S749)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
CLADOSIPHON OKAMURANUS (UNII: 2IJE0CH09J)
INDIGOFERA TINCTORIA LEAF (UNII: 2K7DF8HZDM)
OAT (UNII: Z6J799EAKJ)
STYPHNOLOBIUM JAPONICUM FLOWER (UNII: 644C3CSB6E)
RICE GERM OIL (UNII: D4H5GG5JF)
COCONUT OIL (UNII: Q9L0073W7L)
SILK SERICIN (UNII: 0N1VMU8G9W)
CAPRYLYL/CAPRYL OLIGOGLUCOSIDE (UNII: E00JL9G9K0)
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
TRIHYDROXYSTEARIN (UNII: 06YD7896S3)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
SODIUM DILAURAMIDOGLUTAMIDE LYSINE (UNII: MNJ7VPT2R5)
ETHYLHEXYL PALMITATE (UNII: 2865993309)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
STANNIC OXIDE (UNII: KM7N50LOS6)
MICA (UNII: V8A1AW0880)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69417-140-03	1 in 1 BOX	04/26/2023	
1		10 mL in 1 JAR; Type 0: Not a Combination Product		
2	NDC:69417-140-17	1 in 1 BOX	04/26/2023	
2		50 mL in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	04/26/2023	

Labeler - TATCHA INC. (006811461)

Revised: 6/2023

TATCHA INC.