

INDIGO SOOTHING TRIPLE RECOVERY CREAM- colloidal oatmeal lotion
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.

DRUG FACTS

Purpose

Skin Protectant

Active Ingredients

Colloidal Oatmeal 3.00%

Uses

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

Warnings

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

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Directions

- Apply as needed.

Inactive Ingredients


WATER, SQUALANE, GLYCERIN, PROPANEDIOL, CYCLOPENTASILOXANE, DIISOSTEARYL MALATE, ORYZA SATIVA (RICE) BRAN WAX, XYLITOL, BEHENYL ALCOHOL, POLYGONUM TINCTORIUM (JAPANESE INDIGO) LEAF/STEM EXTRACT, INDIGOFERA TINCTORIA LEAF EXTRACT, AVENA SATIVA (OAT) KERNEL EXTRACT, CAMELLIA SINENSIS (GREEN TEA) LEAF EXTRACT, COCOS NUCIFERA (COCONUT) OIL, SOPHORA JAPONICA FLOWER EXTRACT, PRUNUS LANNESIANA FLOWER EXTRACT, ORYZA SATIVA (RICE) GERM OIL, INOSITOL (RICE EXTRACT), SERICIN (SILK EXTRACT), TETRASODIUM TETRACARBOXYMETHYL NARINGENINCHALCONE, CHONDRUS CRISPUS (RED ALGAE) EXTRACT, AMORPHOPHALLUS KONJAC ROOT POWDER, SODIUM HYALURONATE, DEXTRIN, SORBITAN TRISTEARATE, TRIHYDROXYSTEARIN, DIMETHICONE, DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER, BEHENETH-20, BIS-DIGLYCERYL

POLYACYLADIPATE-2, ETHYLHEXYLGLYCERIN, SODIUM DILAURAMIDOGLUTAMIDE LYSINE, DISODIUM EDTA, ETHYLHEXYL PALMITATE, SODIUM ACRYLATE/ACRYLOYLDIMETHYLTAURATE/ DIMETHYLACRYLAMIDE CROSSPOLYMER, TITANIUM DIOXIDE, CALCIUM CARBONATE, TIN OXIDE, PHENOXYETHANOL, MICA

Other Information

Store at 20-25C (68-77)F

Principal Display Panel

 TETHER 316 OCCIDENTAL AVENUE SOUTH 4th FLOOR, SEATTLE, WASHINGTON 98104 T 206.518.6300 F 206.518.6301 WWW.TETHERINC.COM		COLORS / SPOTS 1. <input type="checkbox"/> PMS --- 2. <input type="checkbox"/> PMS --- 3. <input type="checkbox"/> PMS --- 4. <input type="checkbox"/> PMS --- 5. <input type="checkbox"/> PMS --- 6. <input type="checkbox"/> PMS --- 7. <input type="checkbox"/> PMS --- 8. <input type="checkbox"/> PMS --- 9. <input type="checkbox"/> PMS --- 10. <input type="checkbox"/> PMS --- <input type="checkbox"/> CLEAR TO SUBSTRATE	APPROVAL / CHANGES DATE: _____ OK TO RELEASE: _____ CHECKLIST <table border="1"> <thead> <tr> <th></th> <th>OK</th> <th>OK W/</th> <th>NEEDS</th> </tr> <tr> <th></th> <th>CHANGES</th> <th>CHANGES</th> <th>CHANGES</th> </tr> </thead> <tbody> <tr> <td>CREATIVE DIRECTOR</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>DESIGN DIRECTOR</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>PROJECT MANAGER</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>PRODUCTION MANAGER</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>PRODUCTION DESIGNER</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>DESIGNER</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>DESIGNER</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td>WRITER</td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </tbody> </table>		OK	OK W/	NEEDS		CHANGES	CHANGES	CHANGES	CREATIVE DIRECTOR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	DESIGN DIRECTOR	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	PROJECT MANAGER	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	PRODUCTION MANAGER	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	PRODUCTION DESIGNER	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	DESIGNER	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	DESIGNER	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	WRITER	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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JOB NAME: DELUXE FACE CREAM PHOTO/ILLUS: --- CLIENT: TATCHA PRE-PRESS: --- FILE FORMAT: Illustrator CC PROJ MGR: Alex Warren TRIM: 0.00" x 0.00" DESIGNER: Meg O'Brien BLEED: 0.00" DESIGNER: --- SCALE: 1:1 WRITER: --- USAGE RIGHTS: ---		NOTES: ---																																									



INDIGO SOOTHING TRIPLE RECOVERY CREAM

colloidal oatmeal lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69417-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OATMEAL (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y)	OATMEAL	3 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SQUALANE (UNII: GW89575KF9)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPANEDIOL (UNII: 5965N8W85T)	
DIMETHICONE CROSSPOLYMER (450000 MPAS AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
DIISOSTEARYL MALATE (UNII: QBS8A3XZGQ)	
ORYZA SATIVA WHOLE (UNII: 84IVV0906Z)	
XYLITOL (UNII: VCQ006KQ1E)	
BEHENETH-20 (UNII: BJ4GP2IFLN)	
SODIUM ACRYLATE (UNII: 7C98FKB43H)	
SORBITAN TRISTEARATE (UNII: 6LUM696811)	
DIMETHICONE/DIENE DIMETHICONE CROSSPOLYMER (UNII: RSA9I561OK)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICA (UNII: V8A1AW0880)	
COCOS NUCIFERA WHOLE (UNII: 245J88W96L)	
INOSITOL (UNII: 4L6452S749)	
AMORPHOPHALLUS KONJAC ROOT (UNII: F7KU2UY3HE)	
DISODIUM EDTA-COPPER (UNII: 6V475AX06U)	
INDIGOFERA TINCTORIA LEAF (UNII: 2K7DF8HZDM)	
SERICIN 1 (UNII: N6466G03F7)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CAMELLIA SINENSIS WHOLE (UNII: C5M4585ZBZ)	
CHONDRUS CRISPUS (UNII: OQS23HUA1X)	
AVENA SATIVA WHOLE (UNII: 5P8D0Z74RG)	
PRUNUS APETALA WHOLE (UNII: 70PO4VL8CO)	
SOPHORA FLAVESCENS WHOLE (UNII: X8KX602M5L)	
DEXTRAN 1 (UNII: I8LHQ0D645)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
POLYGONUM ARENASTRUM WHOLE (UNII: M7IQ4O4186)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69417-100-03	10 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 final	part347	06/16/2015	

Labeler - TATCHA INC. (006811461)

