S.O.S. INSTANT RESCUE- dimethicone gel
NATURA BISSÉ INTERNATIONAL, S.A.

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.

PURPOSE

Skin Protectant

INDICATIONS AND USAGE

Helps prevent, temporarily protects and helps relieve chapped or cracked skin.
Helps prevent and protect from the drying effects of wind and cold weather

ACTIVE INGREDIENT

Dimethicone 1%

DOSAGE AND ADMINISTRATION

Apply as needed

INACTIVE INGREDIENTS

Water, Pentylene Glycol, Calendula Officinalis Flower Extract, Methyl Gluceth-10, Propylene Glycol, Butylene Glycol, Aloe Barbadensis Leaf Extract, Sodium Acrylates Copolymer, Panthenol, Allantoin, Lecithin, Glycerin, Arginine, Laureth-3, Arnica Montana Flower Extract, Hydroxyethylcellulose, Propolis Extract, Disodium EDTA, Potassium Sorbate, Acetyl Dipeptide-1 Cetyl Ester, Urea, Lactic Acid, Sodium Lactate, Serine, Sorbitol, Pseudoalteromonas Ferment Extract, Sodium Benzoate, Hydrolyzed Wheat Protein, Sodium Chloride, Hydrolyzed Soy Protein, Ascorbic Acid, Phenoxyethanol, Caprylyl Glycol, Xanthan Gum, Citric Acid, Tripeptide-10 Citrulline, Carbomer, Tripeptide-1, Triethanolamine.

WARNINGS

For external use only
When using this product - do not get into eyes.
Do not use on deep or puncture wounds - animal bites - serious burns.

KEEP OUT OF REACH OF CHILDREN

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

STOP USE

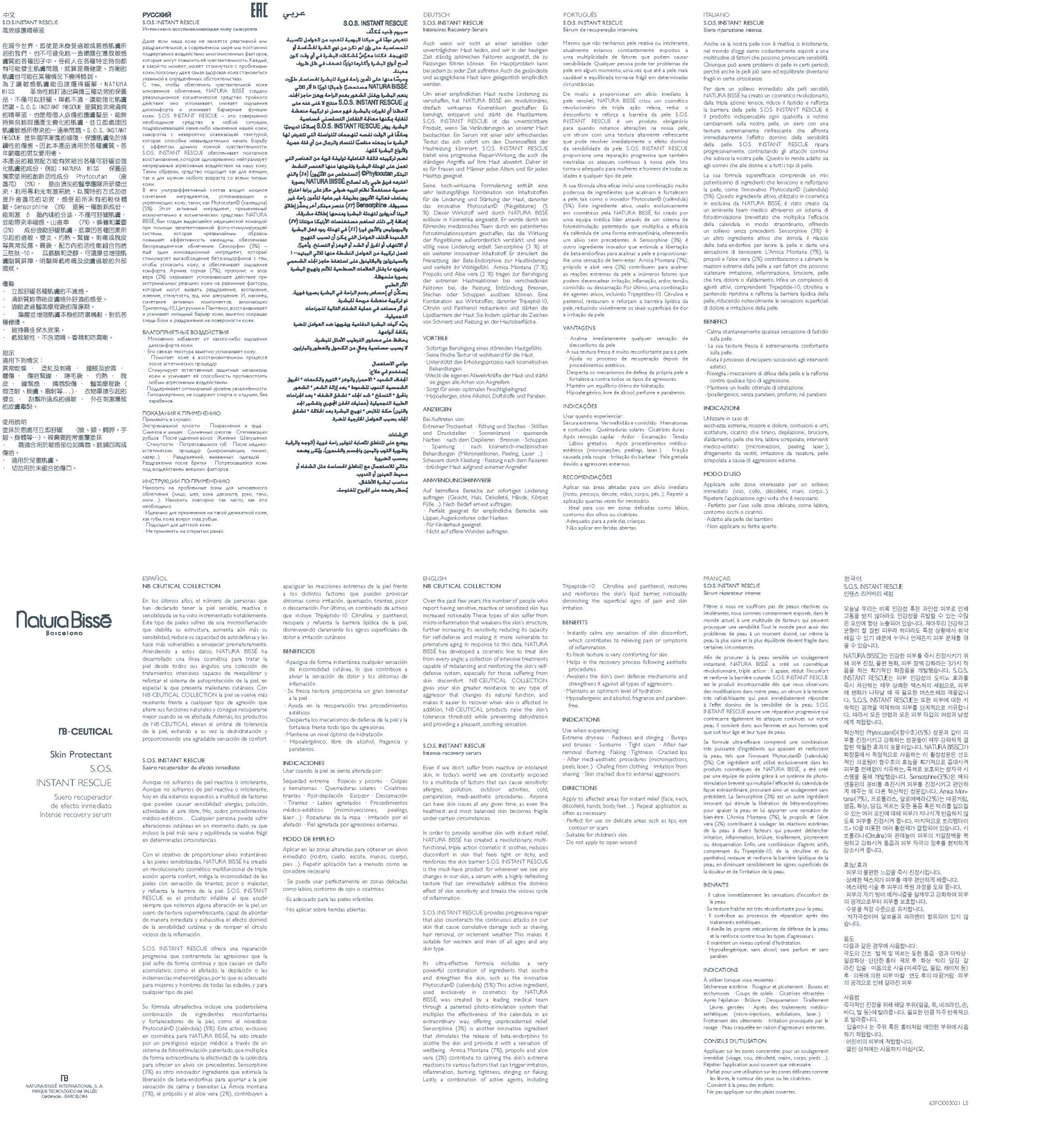
Stop Use and Ask Doctor if conditions worsens - symptoms last more than 7 days or clear up and occur again

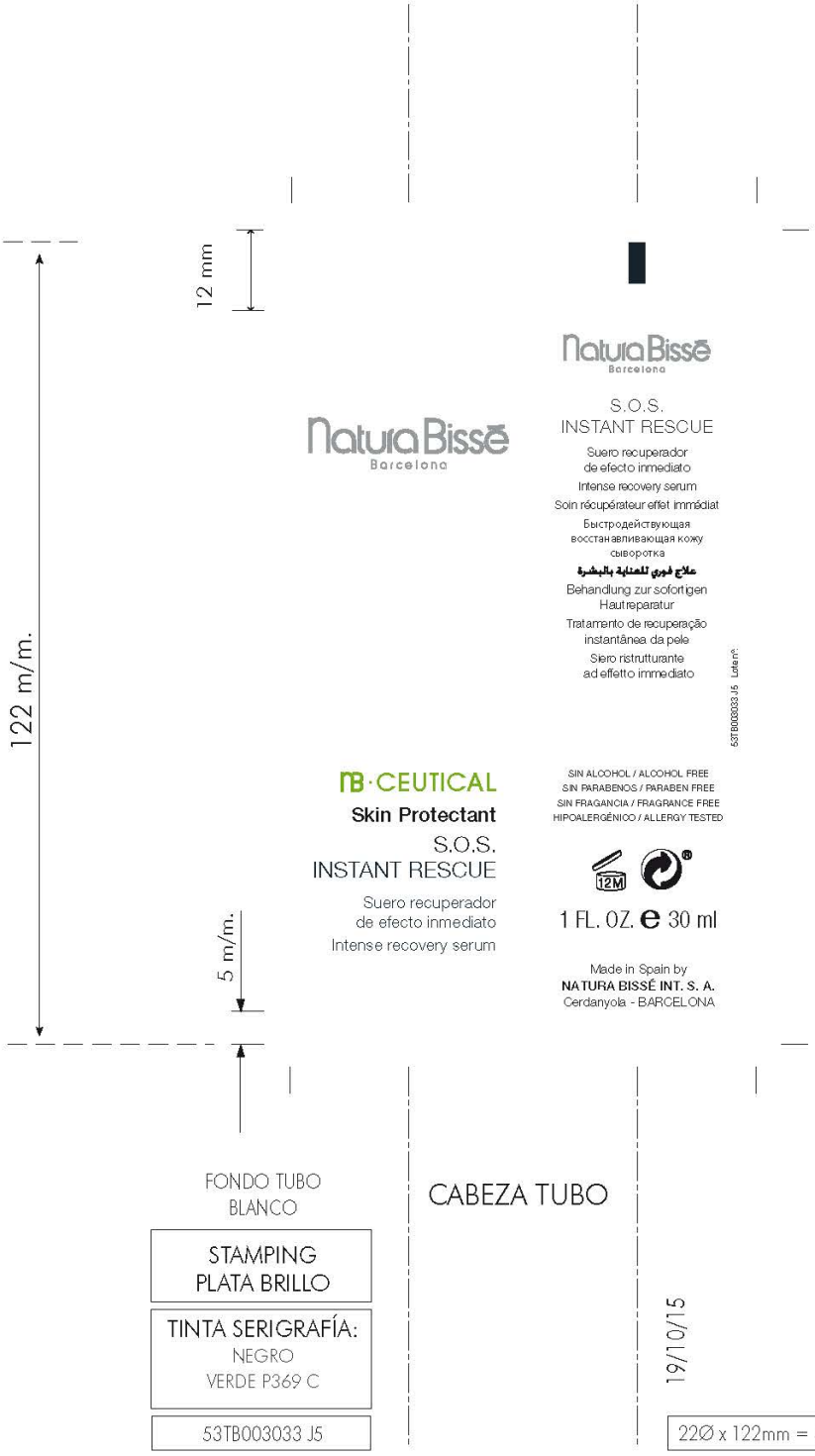
within a few days.

OTHER INFORMATION

Protect this product from excessive heat and direct sun.

PACKAGE LABEL





FONDO TUBO
BLANCO

STAMPING
PLATA BRILLO

TINTA SERIGRAFÍA:
NEGRO
VERDE P369 C

53TB003033 J5

CABEZA TUBO

19/10/15

22Ø x 122mm = 30ml

S.O.S. INSTANT RESCUE

dimethicone gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63730-391

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	1 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
BIOTINOYL TRIPEPTIDE-1 (UNII: O6380721VA)	
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	
1,3-BIS(BENZOTHIAZOL-2-YLTHIOMETHYL)UREA (UNII: 0214C2T14J)	
LACTIC ACID, D- (UNII: 3Q6M5SET7W)	
SODIUM LACTATE (UNII: TU7HW0W0QT)	
ALTEROMONAS MACLEODII (UNII: BPX036043D)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRIPEPTIDE-10 CITRULLINE (UNII: 2732R0E76W)	
PROPYLENE GLYCOL, (R)- (UNII: 602HN5L69H)	
ALLANTOIN, (+)- (UNII: XDK458E1J9)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ARGININE, D- (UNII: R54Z304Z7C)	
LAURETH-3 (UNII: F32E4CB0UJ)	
ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ)	
CETYL HYDROXYETHYLCELLULOSE (550000 MW) (UNII: 2MIM45ZIL3)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
N-ACETYL DIPEPTIDE-1 (UNII: HA41Z1UF8D)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL, L- (UNII: 01Q0586BG1)	
TROLAMINE (UNII: 9O3K93S3TK)	
SODIUM ACRYLATE (UNII: 7C98FKB43H)	
PANTHENOL (UNII: WV9CM0O67Z)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0KO0R)	
SERINE, D- (UNII: 1K77H2Z9B1)	
HYDROLYZED WHEAT PROTEIN (ENZYMATIC, 3000 MW) (UNII: J2S07SB0YL)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
EGTA DISODIUM (UNII: 7T6F42A6GN)	
METHYL GLUCETH-10 (UNII: N0MWT4C7WH)	
HYDROLYZED SOY PROTEIN (ENZYMATIC; 2000 MW) (UNII: 1394NXB9L6)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63730-391-01	30 mg in 1 JAR; Type 0: Not a Combination Product	02/29/2016	03/14/2016
2	NDC:63730-391-02	2 mg in 1 JAR; Type 0: Not a Combination Product	02/29/2016	03/14/2016
3	NDC:63730-391-03	7 mg in 1 JAR; Type 0: Not a Combination Product	02/29/2016	03/14/2016
4	NDC:63730-391-04	30 mg in 1 TUBE; Type 0: Not a Combination Product	03/14/2016	
5	NDC:63730-391-05	2 mg in 1 TUBE; Type 0: Not a Combination Product	03/14/2016	
6	NDC:63730-391-06	7 mg in 1 TUBE; Type 0: Not a Combination Product	03/14/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	02/29/2016	

Labeler - NATURA BISSÉ INTERNATIONAL, S.A. (464431576)

Establishment

Name	Address	ID/FEI	Business Operations
NATURA BISSÉ INTERNATIONAL, S.A.		464431576	manufacture(63730-391)

Revised: 3/2016 NATURA BISSÉ INTERNATIONAL, S.A.