

**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.*

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**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.

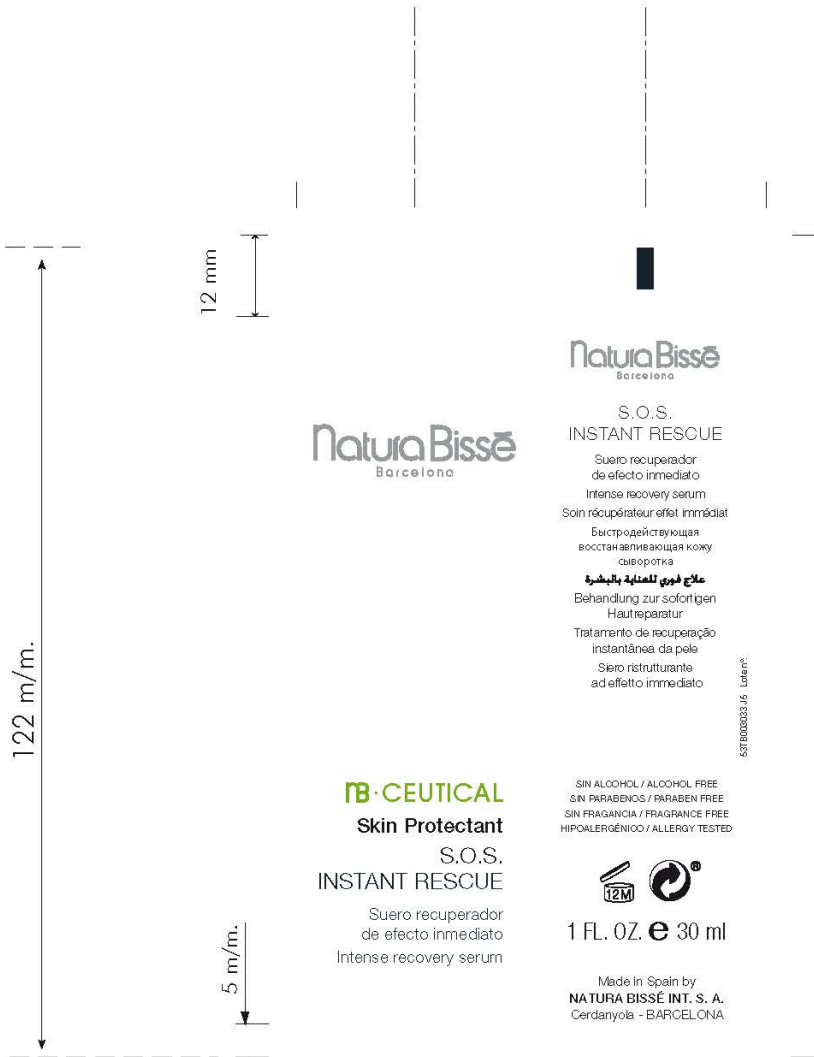
**KEEP OUT OF REACH OF CHILDREN**

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





122 m/m.

12 mm

5 m/m.

**Natura Bissé**  
Barcelona

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Barcelona

S.O.S.  
INSTANT RESCUE

Suero recuperador de efecto inmediato  
Intense recovery serum  
Soin récupérateur effet immédiat  
Быстродействующая восстанавливающая кожу сыворотка  
علاج فوري للمعالجة بالبشرة  
Behandlung zur sofortigen Hautreparatur  
Tratamento de recuperação instantânea da pele  
Siero ristrutturante ad effetto immediato

53TB003033 J5. Label: P

**NB-CEUTICAL**

**Skin Protectant**

S.O.S.  
INSTANT RESCUE

Suero recuperador de efecto inmediato  
Intense recovery serum

SIN ALCOHOL / ALCOHOL FREE  
SIN PARABENOS / PARABEN FREE  
SIN FRAGANCIA / FRAGRANCE FREE  
HIPOALERGÉNICO / ALLERGY TESTED



1 FL. OZ. e 30 ml

Made in Spain by  
NATURA BISSÉ INT. S. A.  
Cerdanyola - BARCELONA

FONDO TUBO  
BLANCO

CABEZA TUBO

STAMPING  
PLATA BRILLO

TINTA SERIGRAFÍA:  
NEGRO  
VERDE P369 C

53TB003033 J5

19/10/15

22Ø x 122mm = 30ml



Natura Bissé  
Barcelona

S.O.S.  
INSTANT RESCUE

Suero recuperador de efecto inmediato  
Intense recovery serum  
Soin récupérateur effet immédiat  
Быстродействующая восстанавливающая  
кожу сыворотка  
علاج فوري للعناية بالبشرة  
Behandlung zur sofortigen Hautreparatur  
Tratamento de recuperação instantânea da pele  
Siero ristrutturante ad effetto immediato

Drug Facts

**Active ingredients** ..... **Purpose**  
Dimethicone 1% ..... Skin Protectant

Uses

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

Warnings

For external use only

When using this product - do not get into eyes.

Stop use and ask a doctor if

- conditions worsen - symptoms last more than 7 days or clear up and occur again within a few days.

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.

Directions

- 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 Dipalmitate-1 Octyl Ester, Urea, Lactic Acid, Sodium Lactate, Stearin, Sorbitol, Passiflorae Ferrous Ferment Extract, Sodium Benzoate, Hydrolyzed Wheat Protein, Sodium Chloride, Hydrolyzed Soy Protein, Ascorbic Acid, Phenoxethanol, Caprylyl Glycol, Xanthan Gum, Citric Acid, Tripeptide-10 Citrulline, Carbomer, Tripeptide-1, Trehaloinamine.

**Other information** protect this product from excessive heat and direct sun.

**Questions?** 1-800-762-8872

Natura Bissé  
Barcelona

IB-CEUTICAL

Skin Protectant

S.O.S.  
INSTANT RESCUE

Suero recuperador de efecto inmediato  
Intense recovery serum

1 FL. OZ. e 30 ml

ESTE PRODUCTO SÓLO PUEDE VENDERSE  
EN ESTABLECIMIENTOS AUTORIZADOS  
POR NATURA BISSE

THIS PRODUCT CAN BE SOLD ONLY BY  
AUTHORIZED NATURA BISSE RETAILERS

Made in Spain by  
NATURA BISSE INT. S. A.  
POUE, TECNOL. del VALLES  
Cerdanyola - BARCELONA

ARNICA MONTANA	7%
PHYTOGLUTÍN* (Caléndula)	5%
SENSORPHINE	3%
ALOE VERA	2%

Ingredients / Ingredientes: WATER (AGUA), PENTYLENE GLYCOL, METHYL GLUCETH-10, CALENDULA OFFICINALIS FLOWER EXTRACT, PROPYLENE GLYCOL, BUTYLENE GLYCOL, ALOE BARBADENSIS LEAF EXTRACT, SODIUM ACRYLATES COPOLYMER, PANTHENOL, DIMETHICONE, ARNICA MONTANA FLOWER EXTRACT, ALLANTOIN, GLYCERIN, ARGININE, PROPOLIS EXTRACT, ACETYL DIPALMITATE-1 CETYL ESTER, UREA, LACTIC ACID, SODIUM LACTATE, STEARIN, SORBITOL, PASSIFLORAE FERMENT EXTRACT, HYDROLYZED WHEAT PROTEIN, HYDROLYZED SOY PROTEIN, TRIPETIDE-10 CITRULLINE, TRIPETIDE-1, LECITHIN, LAURETH-3, HYDROXYETHYLCELLULOSE, DISODIUM EDTA, SODIUM CHLORIDE, ASCORBIC ACID, CAPRYLYL GLYCOL, XANTHAN GUM, CITRIC ACID, CARBOMER, TRIETHANOLAMINE, POTASSIUM SORBATE, SODIUM BENZOATE, PHENOXYETHANOL.

SIN ALCOHOL / ALCOHOL FREE  
SIN PARABENOS / PARABEN FREE  
SIN FRAGRANCIA / FRAGRANCE FREE  
HIPOALERGÉNICO / ALLERGY TESTED

TESTADO BAJO CONTROL  
DERMATOLÓGICO  
TESTED UNDER  
DERMATOLOGICAL CONTROL

Producto hecho en España y exportado por  
NATURA BISSE INT. S. A. Barcelona, España.  
Importado y distribuido en México por  
NATURA BISSE INTERNACIONAL S.A. DE C.V.  
Herschel No. 50 Colonia Anzures. Delegación Miguel Alemán  
C. P. 11500 México, D. F. RFC NB0402132PO

31D201



Cód. 83-CA  
00025  
KS

S.O.S. INSTANT RESCUE

dimethicone gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63730-39 1

## 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(BENZOTHAZOL-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.