

BLACK ROSE- lanolin ointment
MAKRA KOZMETIKA D.O.O.

Black Rose

Drug Facts

Active ingredient

Lanolin 24.91%

Purpose

Skin Protectant

Uses

- temporarily protects minor:
 - temporarily protects chapped or cracked skin
 - helps protect from the drying effects of wind and cold weather
- cuts
- scrapes
- burns

Warnings

For external use only.

Do not use

- on deep or puncture wounds
- on animal bites
- on serious burns

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

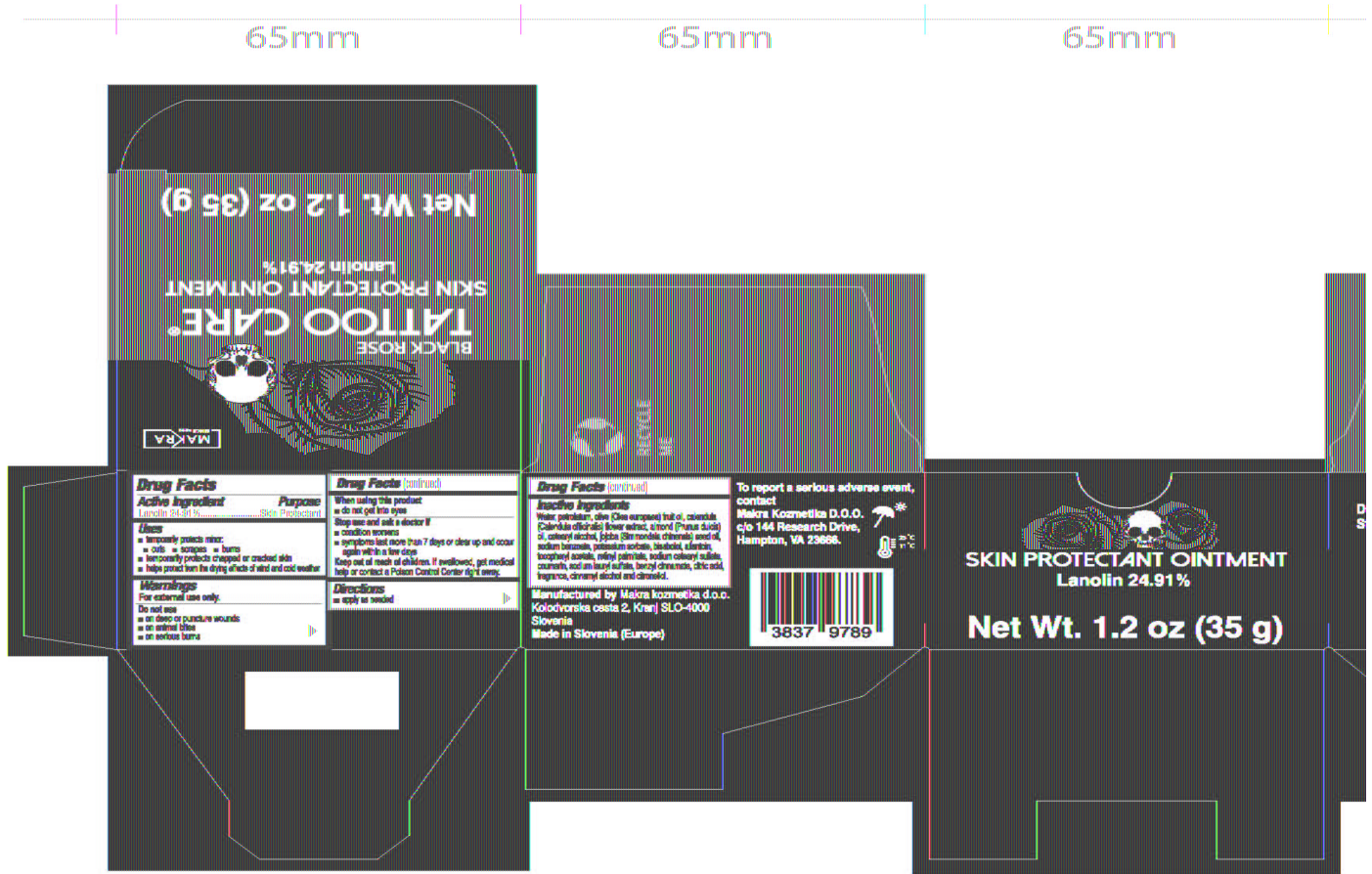
apply as needed

Inactive ingredients

Water, petrolatum, olive (*Olea europea*) fruit oil, calendula (*Calendula officinalis*) flower extract, almond (*Prunus dulcis*) oil, cetearyl alcohol, jojoba (*Simmondsia chinensis*) seed oil, sodium benzoate, potassium sorbate, bisabolol, allantoin, tocopheryl acetate, retinyl palmitate, sodium cetearyl sulfate, coumarin, sodium lauryl sulfate, benzyl cinnamate, citric acid, fragrance, cinnamyl alcohol and citronellol.

Tattoo Care Black Rose Skin Protectant Ointment, 1.2 oz (35g) 82806-100-01





BLACK ROSE

lanolin ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82806-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LANOLIN (UNII: 7EV65EAW6H) (LANOLIN - UNII: 7EV65EAW6H)	LANOLIN	249.1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
PETROLATUM (UNII: 4T6H12BN9U)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD)	
ALMOND OIL (UNII: 66YXD4DKO9)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	

JOJOBA OIL (UNII: 724GKU717M)
SODIUM BENZOATE (UNII: OJ245FE5EU)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
.ALPHA.-BISABOLOL, (+)- (UNII: 105S6I733Z)
ALLANTOIN (UNII: 344S277G0Z)
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)
COUMARIN (UNII: A4VZ22K1WT)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
BENZYL CINNAMATE (UNII: V67O3RO97U)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
CINNAMYL ALCOHOL (UNII: SS8YOP444F)
.BETA.-CITRONELLOL, (R)- (UNII: P01OUT964K)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82806-001-01	1 in 1 CARTON	09/01/2022	
1		35 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 Drug	M016	09/01/2022	

Labeler - MAKRA KOZMETIKA D.O.O. (537064093)

Registrant - MAKRA KOZMETIKA D.O.O. (537064093)

Establishment

Name	Address	ID/FEI	Business Operations
MAKRA KOZMETIKA D.O.O.		537064093	manufacture(82806-001)

Revised: 12/2023

MAKRA KOZMETIKA D.O.O.