

GR BB SPF 25- octinoxate, oxybenzone, titanium dioxide cream
ERKUL KOZMETIK SANAYI VE TICARET ANONIM SirkETI

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.

GR GOLDEN ROSE BB CREAM BEAUTY BALM

Drug Facts

Active ingredients

Octinoxate 2.5% w/v

Oxybenzone 0.25% w/v

Titanium Dioxide 4.95% w/v

Purpose

Sunscreen

Uses

• helps prevent sunburn • if used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use • on damaged or broken skin

When using this product • keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if • rash occurs

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

Directions

• apply generously 15 minutes before the sun exposure • apply to cleansed skin • can be applied two coats to increase coverage • reapply at least every 2 hours • use a water resistant sunscreen if swimming or sweating

• **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a sun Broad Spectrum SPF value of 15 or higher and other protection measures including: • limit time in the sun, especially from 10 a.m. - 2 p.m. • wear long-sleeved shirts, pants,

hats, and sunglasses.

- children under 6 months of age: Ask a doctor

Other information

- protect the product in this container from excessive heat and direct sun.
- store at room temperatures: 15°C- 30°C.

Inactive ingredients

Water (Aqua), Cyclopentasiloxane, Isododecane, Glycerin, PEG-9 Polydimethylsiloxyethyl Dimethicone, Butylene Glycol, Phenyl Trimethicone, Talc, Acrylates/Dimethicone Copolymer, Silica Dimethyl Silylate, Sodium Chloride, Phenoxyethanol, Disteardimonium Hectorite, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethicone, Tocopheryl Acetate, PEG/PPG-18 /18 Dimethicone, White Bird of Paradise (Strelitzia nicolai) Seed Aril Extract, Propylene Carbonate, Pentylene Glycol, Potassium Sorbate, Disodium EDTA, Sorbic Acid, Triethoxycaprylylsilane, Lactic Acid, Serine, Sodium Lactate, Sorbitol, Urea, Magnesium Stearate, Fragrance, Silica, Isoceteth-10, Aluminum Hydroxide, Allantoin, Linalool, Mica*, Iron Oxides*, Bismuth Oxychloride*.

* contains one or more of these ingredients

BB CREAM

BEAUTY BALM

Broad Spectrum SPF 25

All in One, Instantly Perfect Looking Skin!

- Gives a smooth finish look with its light and easy to apply texture.
- Provides hydration to the skin during the day.
- SPF 25 (UVA/UVB) protects your skin against the harmful sunrays.

DERMATOLOGICALLY TESTED

Manufactured By:

ERKUL COSMETICS

San. Tic. A.Ş.

Petrol Ofisi Cad. No:1

Avcılar, Istanbul, Turkey,

34310

Phone: +90 212 456 53 00

www.goldenrose.com.tr

info@goldenrose.com.tr

MADE IN TURKEY

Distributed By:

CELESTY LLC

3970 NW 167 TH ST.

MIAMI GARDENS,
FL 33054 – USA

info@celesty.com

EU R.P. : Platin Beauty Consulting UG (haftungsbeschränkt)
Bardowicker Str. 6, 21335 Lüneburg/GERMANY

Packaging

Inner Package Label

GR
GOLDEN ROSE

BB
CREAM
BEAUTY BALM

**Broad Spectrum
SPF 25**

Instantly Perfect
Looking Skin

1.01 fl. oz. (30 mL)

**GOLDEN ROSE
BB CREAM
BEAUTY BALM**
Broad Spectrum SPF 25

All in One, Instantly Perfect Looking Skin!

- Gives a smooth finish look with its light and easy to apply texture.
- Provides hydration to the skin during the day.
- SPF 25 (UVA/UVB) protects your skin against the harmful sunrays.

DERMATOLOGICALLY TESTED

Manufactured By:
ERKUL COSMETICS San. Tic. A.Ş.
Petrol Ofisi Cad. No:1
Avclar, Istanbul, Turkey, 34310
Phone: +90 212 456 53 00
www.goldenrose.com.tr
info@goldenrose.com.tr

MADE IN TURKEY

Distributed By:
CELESTY LLC
3970 NW 167TH ST, MIAMI GARDENS,
FL 33054 – USA
info@celesty.com

EU R.P.: Platin Beauty Consulting UG (haftungsbeschränkt)
Bardowicker Str. 6, 21335 Lüneburg/GERMANY

Expiry:
Lot no:

Outer Package Label

GR
GOLDEN ROSE

**BB CREAM
BEAUTY BALM**

All in One, Instantly
Perfect Looking Skin!

- Gives a smooth finish look with its light and easy to apply texture.
- Provides hydration to the skin during the day.
- SPF 25 (UVA/UVB) protects your skin against the harmful sunrays.

DERMATOLOGICALLY
TESTED

Drug Facts
(continued)

Inactive ingredients
Acrylates/Dimethicone Copolymer, Silica Dimethyl Silylate, Sodium Chloride, Phenoxyethanol, Disteardimonium Hectorite, Dimethicone/Vinyl Dimethicone Crosspolymer,

Drug Facts

Active ingredients	Purpose
Octinoxate 2.5% w/v	}.....Sunscreen
Oxybenzone 0.25% w/v	
Titanium Dioxide 4.95% w/v	

Uses • helps prevent sunburn • if used as directed with other sun protection measures (see *Directions*), decreases the risk of skin cancer and early skin aging caused by the sun

Warnings
For external use only

Dimethicone,
Tocopheryl Acetate,
PEG/PPG-18/18
Dimethicone, White
Bird of Paradise
(*Strelitzia nicotai*)
Seed Aril Extract,
Propylene Carbonate,
Pentylene Glycol,
Potassium Sorbate,
Disodium EDTA,
Sorbic Acid,
Triethoxycaprylylsilane,
Lactic Acid, Serine,
Sodium Lactate,
Sorbitol, Urea,
Magnesium Stearate,
Fragrance, Silica,
Isoceteth-10,
Aluminum Hydroxide,
Allantoin, Linalool,
Mica*, Iron Oxides*,
Bismuth Oxchloride*.
* contains one or more
of these ingredients

BB CREAM BEAUTY BALM

Broad Spectrum
SPF 25

Instantly Perfect
Looking Skin

1.01 fl. oz. (30 mL)

Manufactured By:
ERKUL COSMETICS
San. Tic. A.Ş.
Petrol Ofisi Cad. No:1
Avclar, Istanbul, Turkey,
34310
Phone: +90 212 456 53 00
www.goldenrose.com.tr
info@goldenrose.com.tr

MADE IN TURKEY

Distributed By:
CELESTY LLC
3970 NW 167TH ST.
MIAMI GARDENS,
FL 33054 - USA
info@celesty.com



For external use only

Do not use • on damaged or broken skin

When using this product • keep out of eyes.
Rinse with water to remove.

Stop use and ask a doctor if • rash occurs

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

Directions • apply generously 15 minutes before
the sun exposure • apply to cleansed skin • can be
applied two coats to increase coverage • reapply
at least every 2 hours • use a water resistant
sunscreen if swimming or sweating

• **Sun Protection Measures.** Spending time in the
sun increases your risk of skin cancer and early skin aging.
To decrease this risk, regularly use a sunscreen with a sun
Broad Spectrum SPF value of 15 or higher and other
protection measures including: • limit time in the sun,
especially from 10 a.m. - 2 p.m. • wear long-sleeved
shirts, pants, hats, and sunglasses.

• children under 6 months of age: Ask a doctor

Other information • protect the product in
this container from excessive heat and direct sun.
• store at room temperatures: 15°C- 30°C.

Inactive ingredients Water (Aqua)
Cyclopentasiloxane, Isododecane, Glycerin,
PEG-9 Polydimethylsiloxyethyl Dimethicone,
Butylene Glycol, Phenyl Trimethicone, Talc, ▶

GR BB SPF 25

octinoxate, oxybenzone, titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82715-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	2.5 g in 100 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	0.25 g in 100 mL
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	4.95 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
ISODODECANE (UNII: A8289P68Y2)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)	

TALC (UNII: 7SEV7J4R1U)
2-ETHYLHEXYL ACRYLATE, METHACRYLATE, METHYL METHACRYLATE, OR BUTYL METHACRYLATE/HYDROXYPROPYL DIMETHICONE COPOLYMER (30000-300000 MW) (UNII: S7ZA3CCJ4M)
SILICA DIMETHYL SILYLATE (UNII: EU2PSP0G0W)
SODIUM CHLORIDE (UNII: 451W47IQ8X)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)
DIMETHICONE (UNII: 92RU3N3Y1O)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)
STRELITZIA NICOLAI WHOLE (UNII: YY9ZE10P9H)
PROPYLENE CARBONATE (UNII: 8D08K3S51E)
PENTYLENE GLYCOL (UNII: 50C1307PZG)
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)
SORBIC ACID (UNII: X045WJ989B)
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)
LACTIC ACID, UNSPECIFIED FORM (UNII: 33X04XA5AT)
SERINE (UNII: 452VLY9402)
SODIUM LACTATE (UNII: TU7HW0W0QT)
SORBITOL (UNII: 506T60A25R)
UREA (UNII: 8W8T17847W)
MAGNESIUM STEARATE (UNII: 70097M6I30)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
ISOCETETH-10 (UNII: 1K92T9919H)
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)
ALLANTOIN (UNII: 344S277G0Z)
LINALOOL, (+/-)- (UNII: D81QY6I88E)
MICA (UNII: V8A1AW0880)
FERRIC OXIDE RED (UNII: 1K09F3G675)
BISMUTH OXYCHLORIDE (UNII: 4ZR792I587)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82715-101-01	1 in 1 CARTON	06/06/2022	
1		30 mL in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:82715-101-02	1 in 1 CARTON	06/06/2022	
2		30 mL in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:82715-101-03	1 in 1 CARTON	06/06/2022	
3		30 mL in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:82715-101-04	1 in 1 CARTON	06/06/2022	
4		30 mL in 1 TUBE; Type 0: Not a Combination		

4		Product		
5	NDC:82715-101-05	1 in 1 CARTON	06/06/2022	
5		30 mL in 1 TUBE; Type 0: Not a Combination Product		
6	NDC:82715-101-06	1 in 1 CARTON	06/06/2022	
6		30 mL 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	part352	06/06/2022	

Labeler - ERKUL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI (525225637)

Establishment

Name	Address	ID/FEI	Business Operations
ERKUL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI		525225637	manufacture(82715-101)

Revised: 5/2022

ERKUL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI