

**GR TOTAL COVER 2 IN 1 FOUNDATION AND CONCEALER SPF 15-
octinoxate lotion
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 TOTAL COVER 2 in 1 Foundation & Concealer

Drug Facts

Active ingredients

Octinoxate 1% 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, Dimethicone, Peg-10 Dimethicone, Phenyl Trimethicone, Peg-9 Polydimethylsiloxyethyl Dimethicone, Polymethylsilsesquioxane/Trimethylsiloxysilicate, Caprylyl Methicone, Trimethylsiloxysilicate, Propylene Glycol, Silica Dimethyl Silylate, Disteardimonium Hectorite, Dimethicone/Vinyl Dimethicone Crosspolymer, Polypropylsilsesquioxane, Sodium Chloride, Zinc Pca, Phenoxyethanol, Silica, Dimethicone Crosspolymer, Peg-12 Dimethicone/Ppg-20 Crosspolymer, Tocopheryl Acetate, Peg/Ppg-18/18 Dimethicone, Talc, Isododecane, Xanthan Gum, Triethoxycaprylylsilane, Titanium Dioxide, Ethylhexylglycerin, Disodium Edta, Isoceteth-10, Fragrance, Magnesium Stearate, Aluminum Hydroxide, Linalool. * Iron Oxides. *contains one or more of these ingredients.

SPF 15

Vitamin E

01 PORCELAIN

- Full Coverage & Longwear
- Semi-Matte & Smooth Finish
- Lightweight/Non-Oily Formula

DERMATOLOGICALLY TESTED

ERKUL KOZMETIK San. Tic. A.Ş.,
P.Ofisi Cd. No:1 Avclar, IST./TURKEY

MADE IN TURKEY

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


Packaging

PRIMARY PACK LABEL

Front




Inside



Inside



GOLDEN ROSE



TOTAL COVER
2in1 Foundation
& Concealer
SPF 15

GOLDEN ROSE
TOTAL COVER
2in1 Foundation
& Concealer
SPF 15
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Bardowicker Str. 6,
21335 Lüneburg/GERMANY




30ml e 1.01 fl.oz.

1F14A

FRONT


REAR

SLEEVE



8 691190 963613

01
PORCELAIN



30ml
NET Wt.
1.01fl.oz.

GR TOTAL COVER 2in1 Foundation&Concealer

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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.
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OPEN HERE



GR TOTAL COVER 2 IN 1 FOUNDATION AND CONCEALER SPF 15

octinoxate lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82715-106
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1 g in 100 mL
Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0K00R)		
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)		
DIMETHICONE (UNII: 92RU3N3Y1O)		
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)		
PHENYL TRIMETHICONE (UNII: DR0K5NOJ4R)		
PEG-9 POLYDIMETHYLSILOXYETHYL DIMETHICONE (UNII: TYP81E471F)		
POLYMETHYLSILSESQUIOXANE/TRIMETHYLSILOXYSILICATE (UNII: X2PZH4Y6HT)		
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)		
TRIMETHYLSILOXYSILICATE (M/Q 0.6-0.8) (UNII: 5041RX63GN)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SILICA DIMETHYL Silylate (UNII: EU2PSP0G0W)		
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)		
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)		
PROPYLSILSESQUIOXANE, HYDROGEN TERMINATED (UNII: 2PDG9JR76G)		
SODIUM CHLORIDE (UNII: 451W47IQ8X)		
ZINC PIDOLATE (UNII: C32PQ86DH4)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)		
PEG-12 DIMETHICONE/PPG-20 CROSSPOLYMER (UNII: 965K72OQXO)		
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		
PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794)		
TALC (UNII: 7SEV7J4R1U)		
ISODODECANE (UNII: A8289P68Y2)		
XANTHAN GUM (UNII: TTV12P4NEE)		
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)		
ISOCETETH-10 (UNII: 1K92T9919H)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)		
LINALOOL, (+/-)- (UNII: D81QY6I88E)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)		
FERROSFERRIC OXIDE (UNII: XM0M87F357)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82715-106-01	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	

2	NDC:82715-106-02	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
3	NDC:82715-106-03	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
4	NDC:82715-106-04	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
5	NDC:82715-106-05	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
6	NDC:82715-106-06	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
7	NDC:82715-106-07	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
8	NDC:82715-106-08	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
9	NDC:82715-106-09	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
10	NDC:82715-106-10	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
11	NDC:82715-106-11	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
12	NDC:82715-106-12	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
13	NDC:82715-106-13	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
14	NDC:82715-106-14	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
15	NDC:82715-106-15	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
16	NDC:82715-106-16	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
17	NDC:82715-106-17	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
18	NDC:82715-106-18	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
19	NDC:82715-106-19	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
20	NDC:82715-106-20	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
21	NDC:82715-106-21	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
22	NDC:82715-106-22	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
23	NDC:82715-106-23	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
24	NDC:82715-106-24	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	
25	NDC:82715-106-25	30 mL in 1 TUBE; Type 0: Not a Combination Product	07/22/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	07/22/2022	

Establishment

Name	Address	ID/FEI	Business Operations
ERKUL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI		525225637	manufacture(82715-106)

Revised: 7/2022

ERKUL KOZMETIK SANAYI VE TICARET ANONIM SIRKETI