# CLAPIEL REVITAL SERUM- dimethicone cream AUS KOREA CO., LTD.

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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#### ACTIVE INGREDIENT

Active Ingredient: Dimethicone 20.0%

#### INACTIVE INGREDIENT

Inactive Ingredients: Cyclopentasiloxane, Squalane, Simmondsia Chinensis (Jojoba) Seed Oil, Cyclohexasiloxane, Linum Usitatissimum (Linseed) Seed Oil, Camellia Japonica Seed Oil, Macadamia Ternifolia Seed Oil, Helianthus Annuus (Sunflower) Seed Oil, Rosmarinus Officinalis (Rosemary) Leaf Extract, Pichia Anomala Extract, Yeast Extract, Myrothamnus Flabellifolia Callus Culture Extract, Pentylene Glycol, Hydrolyzed Myrtus Communis Leaf Extract, Undaria Pinnatifida Extract, Lactuca Indica Extract, Corydalis Ochotensis Extract, Draba Nemorosa Extract, Chenopodium Album Flower Extract, Lactobacillus/Soybean Ferment Extract, Salix Alba (Willow) Bark Extract, Cinnamomum Cassia Bark Extract, Origanum Vulgare Leaf Extract, Chamaecyparis Obtusa Leaf Extract, Scultellaria Baicalensis Root Extract, Portulaca Oleracea Extract

#### **PURPOSE**

Purpose: Skin Protectant

#### **WARNINGS**

Warnings: 1. In case of having following symptoms after using this, you're advised to stop using it immediately. If you keep using it, the symptoms will get worse and need to consult a dermatologist. 1) In case of having problems such as red rash, swollenness, itching, stimulation during usage. 2) In case of having the same symptoms above on the part you put this product on by direct sunlight. 2. You are banned to use it on the part where you have a scar, eczema, or dermatitis. 3. In case of getting it into your eyes, you have to wash it immediately.

#### KEEP OUT OF REACH OF CHILDREN

Keep out of reach of babies and children

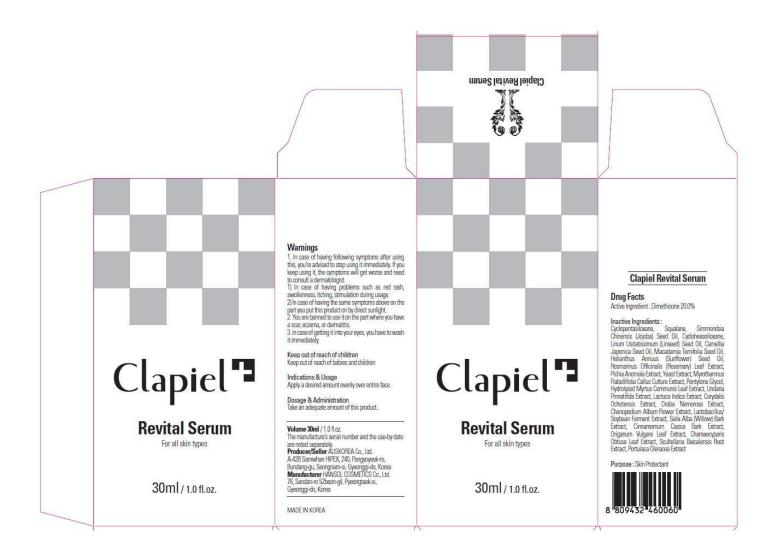
#### INDICATIONS & USAGE

Indications & Usage: Apply a desired amount evenly over entire face.

#### **DOSAGE & ADMINISTRATION**

Dosage & Administration: Take an adequate amount of this product.

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



#### **CLAPIEL REVITAL SERUM**

dimethicone cream

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:69977-040

Route of Administration TOPICAL

#### **Active Ingredient/Active Moiety**

Ingredient NameBasis of StrengthStrengthDimethicone (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)Dimethicone6.0 mg in 30 mL

#### **Inactive Ingredients**

Ingredient Name	Strength
Squalane (UNII: GW89575KF9)	
JOJOBA OIL (UNII: 724GKU717M)	

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Item Code Package Description Marketing Start Date Marketing End Date

1 NDC:69977-040-01 3	0 mL in 1 CARTON; Type 0: Not a Combination Product				
Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph final	part347	05/01/2015			

## Labeler - Aus Korea Co., Ltd. (689515251)

### Registrant - Aus Korea Co., Ltd. (689515251)

Establishment					
Name	Address	ID/FEI	Business Operations		
AUS KOREA CO., LTD.		689515251	manufacture(69977-040)		

Revised: 7/2015 AUS KOREA CO., LTD.