

AWAKEN SKIN PERFECTOR BB BROAD SPECTRUM SPF 15 SUNSCREEN MEDIUM DARK- octinoxate and titanium dioxide cream

Chain Drug Marketing Association

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.

Awaken by Quality Choice® BB Cream Medium/Dark Broad Spectrum SPF 15 Sunscreen

Active ingredients

Octinoxate, 4.0%

Titanium Dioxide, 2.1%

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 liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours

- Use water resistant sunscreen if swimming or sweating
- Children under 6 months of age: ask a doctor
- **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 Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeved shirts, pants, hats and sunglasses

Other Information

- protect the product in this container from excessive heat and direct sun

Inactive Ingredients

water, talc, C12-15 alkyl benzoate, caprylic/capric triglyceride, potassium cetyl phosphate, cyclopentasiloxane, glyceryl myristate, isononyl isononanoate, behenyl alcohol, mineral oil, glycerin, propylene glycol, microcrystalline cellulose, cellulose gum, phenoxyethanol, ethylhexylglycerin, iron oxides, nylon-12, fragrance, triethanolamine, ammonium acryloyldimethyltaurate/VP copolymer, butylene glycol, allantoin, caffeine, ascorbyl glucoside, disodium EDTA, tocopheryl acetate (vitamin E), BHT, hyaluronic acid.

Package/Label Principal Display Panel

Awaken by Quality Choice®

**BB cream
medium/dark**

Broad Spectrum
SPF 15 Sunscreen

Skin perfector

With vitamin C & mineral pigments

Renews, brightens, evens tone & hydrates

Oil free, non-greasy

*Compare to Garnier® Skin Renew Miracle Skin Perfector B.B. Cream SPF15

2.5 FL OZ (75 mL)

This BB Cream medium/dark Broad Spectrum SPF15 Sunscreen is a unique innovation that combines many steps of your daily beauty routine into one.

It is lightweight, easy to use, and provides almost instant results that you can see and feel. This innovative formula is designed to deeply moisturize and help even skin tone, resulting in a smooth and unblemished appearance.

The Results

Skin instantly looks more even-toned, smooth and radiant.

- Radiance is renewed.
- Complexion is brightened.
- Skin tone is evened out and imperfections are blurred.
- 24-hour hydration.

- SPF15 sunscreen protects against the harmful effects of the sun.

Directions for Use

Gently smooth BB Cream Broad Spectrum SPF 15 Sunscreen onto face and neck prior to exposure to the sun.

Formula essentials:

- Dermatology tested
- Non-Comedogenic (won't clog pores)
- Gentle to skin
- Non-greasy

Why is this product for me?

Skin discolorations, dullness, blemishes and dryness can be caused by a number of different factors. It is difficult to find one product that will address all these factors at once.

This product is not manufactured or distributed by Garnier®, owner of the registered trademark Skin Renew

Satisfaction Guaranteed

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Manufactured in ISRAEL

6D118 CD C1

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BB cream medium/dark

BROAD SPECTRUM SPF 15 SUNSCREEN

Skin perfector

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Oil free, non-greasy



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25 FL OZ (75 mL)

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Drug Facts

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Carton Label

AWAKEN SKIN PERFECTOR BB BROAD SPECTRUM SPF 15 SUNSCREEN MEDIUM DARK

octinoxate and titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-253
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	4 g in 100 mL

TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)

TITANIUM DIOXIDE

2.1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
TALC (UNII: 7SEV7J4R1U)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
GLYCERYL MYRISTATE (UNII: 6992Y81827)	
ISONONYL ISONONANOATE (UNII: S4V5BS6GCX)	
DOCOSANOL (UNII: 9G1OE216XY)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
FERROUS OXIDE (UNII: G7036X8B5H)	
NYLON-12 (UNII: 446U8J075B)	
TROLAMINE (UNII: 9O3K93S3TK)	
AMMONIUM ACRYLOYLDIMETHYLAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
ALLANTOIN (UNII: 344S277G0Z)	
CAFFEINE (UNII: 3G6A5W338E)	
ASCORBYL GLUCOSIDE (UNII: 2V52R0NHXW)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
HYALURONIC ACID (UNII: S270N0TRQY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-253-03	1 in 1 CARTON		
1		75 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	09/01/2014	

