OBAGI 360 HYDRAFACTOR MOISTURIZING BROAD SPECTRUM SPF 30 SUNSCREENavobenzone, octinoxate, octis alate, and oxybenzone cream OBAGI COSMECEUTICAL LLC

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.

Obagi 360[®] HydraFactor™ Moisturizing Cream with Sunscreen Broad Spectrum SPF 30 Drug Facts

Active ingredients	Purpose
Avobenzone 1%	Sunscreen
Octinoxate 7.5%	Sunscreen
Octisalate 5%	Sunscreen
Oxybenzone 5%	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

Stop use and ask a doctor if rash occurs

When using this product keep out of eyes. If product gets into eyes, rinse with water to remove.

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
- use a water resistant sunscreen if swimming or sweating
- reapply at least every 2 hours
- **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
- children under 6 months: Ask a doctor

Other information

- store at controlled room temperature: 15°C–25°C (59°F–77°F)
- protect this product from excessive heat and direct sun

Inactive ingredients

water (aqua), C12-15 alkyl benzoate, butyloctyl salicylate, glycerin, sodium hyaluronate, eperua falcata bark extract, dextrin, polysorbate 20, hydrolyzed caesalpinia spinosa gum, caesalpinia spinosa gum, sodium hydroxide, carbomer, acrylates/C10-30 alkyl acrylate crosspolymer, caprylyl glycol, disodium EDTA, hexylene glycol, pichia/resveratrol ferment extract, sorbitan oleate, tocopheryl acetate, ubiquinone, phenoxyethanol, ethylhexylglycerin

Questions or comments?

1.800.636.7546

Monday–Friday 9 a.m.–4 p.m. Pacific Time Distributed by Obagi Cosmeceuticals LLC, Long Beach, CA 90806

PRINCIPAL DISPLAY PANEL - 75 g Tube Carton

OBAGI[®] MEDICAL

OBAGI360®

HydraFactorTM Moisturizing Cream with Sunscreen

Broad Spectrum SPF 30

Net wt. 2.5 oz. (75 g)

OBAGI 360 HYDRAFACTOR MOISTURIZING BROAD SPECTRUM SPF 30 SUNSCREEN

avobenzone, octinoxate, octisalate, and oxybenzone cream

Product Type HUMAN OTC DRUG Item Code (Source) NDC:62032-300

Route of Administration TOPICAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	10 mg in 1 g	
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g	
OCTISALATE (UNII: 4X49 Y0596W) (OCTISALATE - UNII:4X49 Y0596W)	OCTISALATE	50 mg in 1 g	
OXYBENZONE (UNII: 9500S7VE0Y) (OXYBENZONE - UNII:9500S7VE0Y)	OXYBENZONE	50 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER COPOLYMER TYPE A (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 71DD5V995L)		
BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8 D3)		
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)		
CAESALPINIA SPINO SA RESIN (UNII: WL3883U2PO)		
CAPRYLIC ALCOHOL (UNII: NV1779205D)		
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
ICODEXTRIN (UNII: 2NX48Z0A9G)		
EDETATE DISO DIUM (UNII: 7FLD9 1C8 6 K)		
EPERUA FALCATA BARK (UNII: L43J05M2KO)		
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)		
GLYCERIN (UNII: PDC6A3C0OX)		
HEXYLENE GLYCOL (UNII: KEH0 A3F75J)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
POLYSORBATE 20 (UNII: 7T1F30V5YH)		
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)		
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)		
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)		
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)		
UBIDECARENO NE (UNII: EJ27X76M46)		
WATER (UNII: 059QF0KO0R)		

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Product	('haractaristics

Color WHITE Score

Shape	Size	
Flavor	Imprint Code	
Contains		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:62032-300-37	1 in 1 CARTON	0 1/0 2/20 14	12/31/2019	
1		75 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:62032-300-09	1 in 1 CARTON	0 1/0 1/20 20		
2		75 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 final	part352	0 1/0 2/20 14	

Labeler - OBAGI COSMECEUTICAL LLC (790553353)

Establishment			
Name	Address	ID/FEI	Business Operations
G.S Cosmeceutical		017014734	MANUFACTURE(62032-300), LABEL(62032-300), PACK(62032-300)

Revised: 9/2019 OBAGI COSMECEUTICAL LLC