MELAMIX SKIN LIGHTENER AND BLENDING- hydroquinone cream
ZO Skin Health, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

MELAMIX™ Skin Lightener and Blending Crème

Melamin™ contains 4% Hydroquinone, which is used for the treatment of pigmentation problems. It helps to even color tone by inhibiting melanin production.

Indicated for the gradual bleaching of hyperpigmented skin conditions such as chloasma, melasma, freckles, senile lentigines, and other unwanted areas of hyperpigmentation.

DOSAGE AND ADMINISTRATION

Apply 2 pumps (1 g) to affected areas twice a day or as directed by a physician. Always use sunscreen protection. (See enclosed package insert for full prescribing information.)

WARNINGS

Keep out of reach of children.

Contains Sodium Metabisulfite, a sulfite that may cause serious allergic-type reactions including anaphylactic symptoms (e.g. hives, itching), and life threatening or less severe asthmatic episodes in certain susceptible persons.

For external use only. Avoid contact with the eyes.

Some users may experience a mild skin irritation. If skin irritation becomes severe, stop use and consult a physician.

Do not use on children under 12 years of age unless directed by a physician.

If swallowed, get medical help or contact a Poison Control Center right away.

SUNBURN ALERT

This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for a week afterwards.

STORAGE

Store at controlled room temperature: 15°-30°C (59°-86°F), away from direct sunlight.

ACTIVE INGREDIENT

Hydroquinone 4%

INACTIVE INGREDIENTS

Water (Aqua), Glycolic Acid, Glycerin, Cetyl Alcohol, Ethylhexyl Palmitate, Ascorbic Acid, Sodium Lauryl Sulfate, Phenyl Trimethicone, Saponins, Tocopheryl Acetate, Methylparaben, Propylparaben, Sodium Metabisulfite, BHT, Disodium EDTA.

DIST BY

ZO Skin Health, Inc. Irvine, CA 92618

PRINCIPAL DISPLAY PANEL - 80 g Bottle Carton

ZO®MEDICAL
BY **ZEIN OBAGI,** MD

NDC 42851-031-80

08^{rx}

MELAMIX™
Skin Lightener &
Blending Crème

Hydroquinone USP, 4%

RX ONLY

Net Wt. 80 g / 2.8 Oz.

PART OF DR. OBAGI'S
ZO® SKIN HEALTH CIRCLE™

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MADE IN USA 080100

zomedical.com

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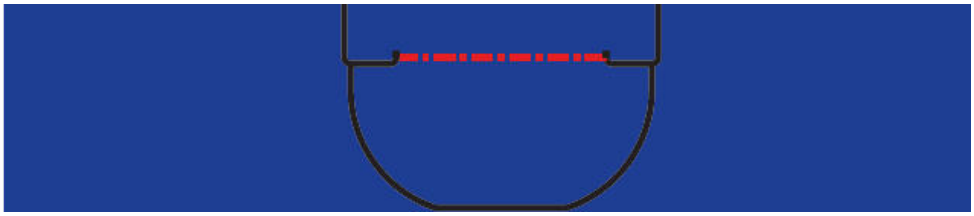

MELAMIX SKIN LIGHTENER AND BLENDING

hydroquinone cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42851-031
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Hydroquinone (UNII: XV74C1N1AE) (Hydroquinone - UNII:XV74C1N1AE)	Hydroquinone	0.04 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
Ascorbic Acid (UNII: PQ6CK8PD0R)	
Butylated Hydroxytoluene (UNII: 1P9D0Z171K)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Edetate Disodium (UNII: 7FLD91C86K)	
Ethylhexyl Palmitate (UNII: 2865993309)	
Glycerin (UNII: PDC6A3C0OX)	
Glycolic Acid (UNII: 0WT12SX38S)	
Methylparaben (UNII: A2I8C7HI9T)	
Phenyl Trimethicone (UNII: DR0K5NOJ4R)	
Propylparaben (UNII: Z8IX2SC1OH)	
Water (UNII: 059QF0KO0R)	
CAULOSIDE D (UNII: 4N5Z068GAZ)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Sodium Metabisulfite (UNII: 4VON5FNS3C)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:42851-031-80	1 in 1 CARTON		
1		80 g in 1 BOTTLE, PLASTIC		
2	NDC:42851-031-32	1 in 1 CARTON		
2		32 g in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/2012	

Labeler - ZO Skin Health, Inc. (826468527)

Establishment

Name	Address	ID/FEI	Business Operations
Sanitor Coporation		797472792	MANUFACTURE(42851-031)

Revised: 4/2014 ZO Skin Health, Inc.