

MELANO OUT MASK- glycerin, mineral oil, allantoin cream
MESO SYSTEM S.A.

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.

MELANO OUT MASK CREAM

Warnings

Stop use and ask a Doctor if rash occurs

WARNINGS

- **For external use only.**
- Do no use on damaged or broken skin
- Stop use and ask a doctor if rash occurs
- Avoid the product from entering your eyes
- Children under 6 months Ask a Doctor

USES

- Mask formulated to attenuate and eliminate coetanous spots of melanic origin located at epidemic levels.
- Keep out of the reach of chuldren.
- In case of overdose get medical help or Contact a Poison Control Center right away.

DIRECTIONS

- Clean the skin thoroughly before applying the mask
- Covered the entire skin with a thin layer
- Single use

QUESTIONS OR COMMENTS ?

- +35 1227347125 M-F: 9:00 am to 5:00 pm

ACTIVE INGREDIENTS

Active Ingredients Purpose

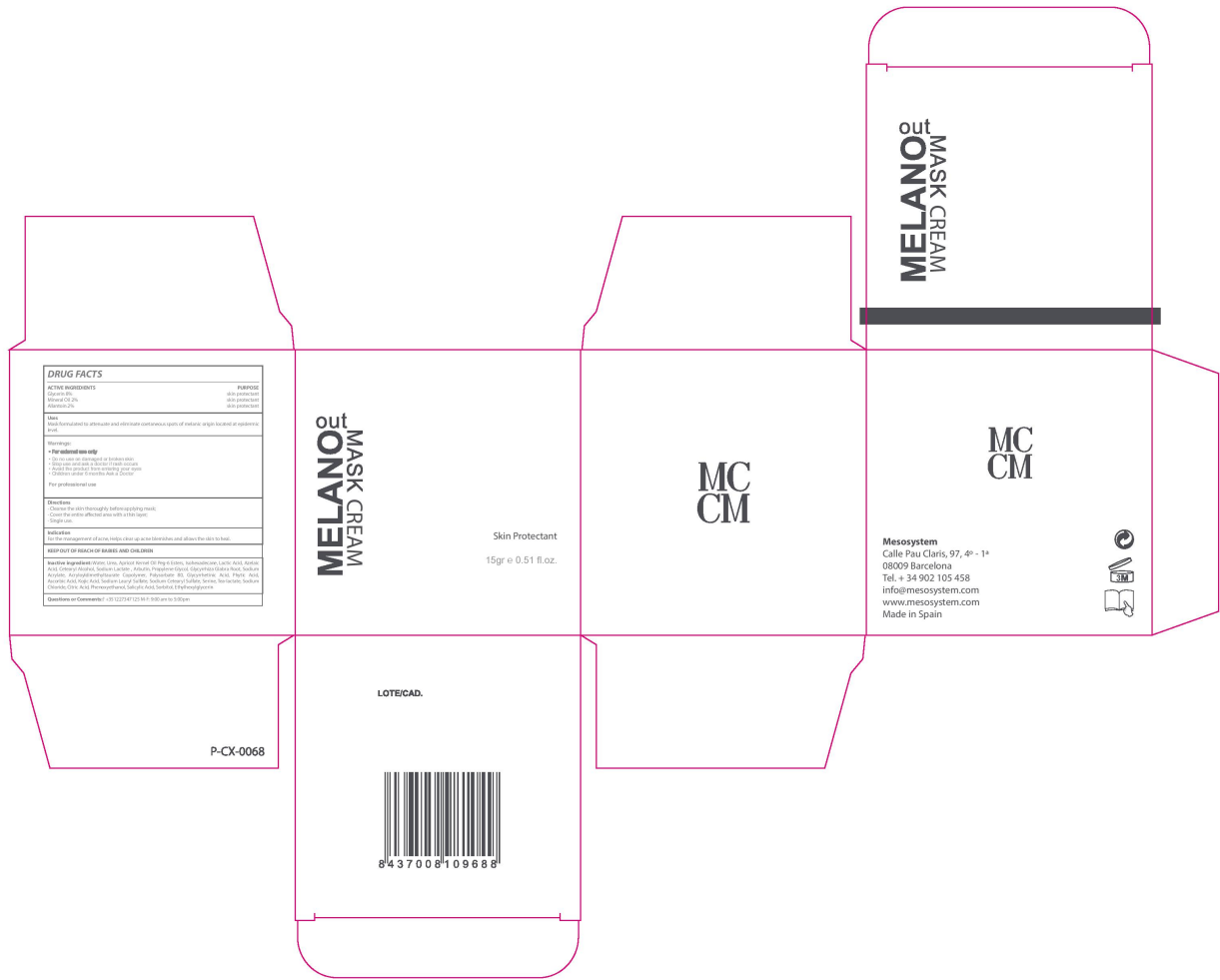
Glycerin 2%.....Skin Protectant

Mineral Oil 2%.....Skin Protectant

Allantoin 2%.....Skin Protectant

Inactive Ingredients

Water, Urea, Apricot Kernel Oil Peg-6 Esters, Isohexadecane, Lactic Acid, Azelaic Acid, Cetearyl Alcohol, Sodium Lactate, Arbutin, Propylene Glycol, Glycyrrhiza Glabra Root, Sodium Acrylate, Acryloyldimethyltaurate Copolymer, Polysorbate 80, Glycyrrhetic Acid, Phytic Acid, Ascorbic Acid, Kojic Acid, Sodium Lauryl Sulfate, Sodium Cetearyl Sulfate, Serine, Tea-lactate, Sodium Chloride, Citric Acid, Phenoxyethanol, Salicylic Acid, Sorbitol, Ethylhexylglycerin



- Mask formulated to attenuate and eliminate coetaneous spots of melanic origin located at epidemic levels.

MELANO OUT MASK CREAM

MELANOout
MASK CREAM

Skin Protectant

15gr. e 0.51 fl.oz.

DRUG FACTS	
ACTIVE INGREDIENTS	PURPOSE
Glycerin 8%	skin protectant
Mineral Oil 2%	skin protectant
Allantoin 2%	skin protectant
KEEP OUT OF REACH OF BABIES AND CHILDREN	
If product is swallowed, get medical help or contact a poison control center right away.	

Inactive ingredients: Water, Urea, Apricot Kernel Oil PEG-6 Ester, Isohexadecane, Lactic Acid, Aspartic Acid, Glycerol Alcohol, Sodium Lactate, Aduronic Propylene Glycol, Glycyrrhiza Glabra Root, Sodium Acrylate, Acryloylurethaneacrylate Copolymer, Polysorbate 80, Glycyrrhizic Acid, Phytic Acid, Ascorbic Acid, Kojic Acid, Sodium Lauryl Sulfate, Sodium Citrate, Sodium Sulfate, Serine, Stearic Acid, Sodium Chloride, Citric Acid, Phenylethanol, Salicylic Acid, Sorbitol, Ethylhexylglycerin.

Warnings:
For external use only
Do no use on damaged or broken skin
Stop use and ask a doctor if rash occurs
Avoid the product from entering your eyes
Children under 6 months Ask a Doctor

Uses
Mask formulated to attenuate and eliminate coetaneous spots of melanic origin located at epidemic level.

Directions
Cleanse the skin thoroughly before applying mask;
Cover the entire affected area with a thin layer;
Single use.

Indication
For the management of acne. Helps clear up acne blemishes and allows the skin to heal.

KEEP OUT OF REACH OF BABIES AND CHILDREN

Questions or Comments: +351227347125 M-F: 9:00 am to 5:00pm



MELANO OUT MASK

glycerin, mineral oil, allantoin cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70663-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	8 mg in 1 mL

ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	2 mg in 1 mL
MINERAL OIL (UNII: T5L8T28FGP) (MINERAL OIL - UNII:T5L8T28FGP)	MINERAL OIL	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SORBITOL (UNII: 506T60A25R)	0.1 mg in 1 mL
ISOHEXADECANE (UNII: 918X10UF1E)	3 mg in 1 mL
WATER (UNII: 059QF0K00R)	38.8 mg in 1 mL
LACTIC ACID (UNII: 33X04XA5AT)	3 mg in 1 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.9 mg in 1 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.1 mg in 1 mL
APRICOT KERNEL OIL PEG-6 ESTERS (UNII: DRG3KJZ1TJ)	3 mg in 1 mL
UREA HYDROCHLORIDE (UNII: RCE1061F6A)	8 mg in 1 mL
AZELAIC ACID (UNII: F2VW3D43YT)	2 mg in 1 mL
ISOSTEARYL ALCOHOL (UNII: Q613OCQ44Y)	2 mg in 1 mL
SODIUM LACTATE (UNII: TU7HW0W0QT)	2 mg in 1 mL
ARBUTIN (UNII: C5INA23HXF)	2 mg in 1 mL
PROPANEDIOL (UNII: 5965N8W85T)	2 mg in 1 mL
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	2 mg in 1 mL
SODIUM ACRYLATE (UNII: 7C98FKB43H)	2 mg in 1 mL
SODIUM ACRYLATE/SODIUM ACRYLO YLDIMETHYLTAURATE COPOLYMER (400000 MW) (UNII: 1DXE3F3OZX)	2 mg in 1 mL
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	2 mg in 1 mL
ENOXOLONE (UNII: P540XA09DR)	2 meq in 1 mL
FYTIC ACID (UNII: 7IGF0S7R8I)	2 mg in 1 mL
ASCORBIC ACID (UNII: PQ6CK8PD0R)	2 mg in 1 mL
KOJIC ACID (UNII: 6K23F1TT52)	1 mg in 1 mL
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	1 mg in 1 mL
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	1 mg in 1 mL
SERINE (UNII: 452VLY9402)	1 mg in 1 mL
TRIETHANOLAMINE LACTATE (UNII: 064C51N81O)	1 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	1 mg in 1 mL
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	1 mg in 1 mL
SALICYLIC ACID (UNII: O414PZ4LPZ)	0.1 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70663-010-02	15 in 1 BOX	12/18/2016	
1	NDC:70663-010-01	15 mL in 1 CYLINDER; 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	12/18/2016	

Labeler - MESO SYSTEM S.A. (768263100)

Registrant - MESO SYSTEM S.A. (768263100)

Establishment

Name	Address	ID/FEI	Business Operations
MESO SYSTEM S.A.		768263100	manufacture(70663-010)

Revised: 12/2016

MESO SYSTEM S.A.