

**MELANO OUT CREAM- allantoin, glycerin 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.*

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**Melano Out 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**

- Cream formulated to attenuate and eliminate the coetaneous spot of melanic origin located at the epidermic level
- 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 cream.
- Cover the entire affected area with a thin layer. First week apply three times daily (morning-afternoon-night). Second week apply two times daily (morning-night). Third week apply once a day for one year.
- During summer it is recommended the application of the cream after sun exposure. If bothersome dryness or peeling occurs, reduce application to once a day or every other day

**QUESTIONS OR COMMENTS ?**

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

**ACTIVE INGREDIENTS**

**Active Ingredients Purpose**

Allantoin 0.01%.....Skin Protectant  
Glycerin 0.25%.....Skin Protectant

**Inactive Ingredients**

Water, Azelaic Acid, Mineral Oil, Ethylhexyl Methoxycinnamate, Cetearyl Alcohol, Salicylic Acid, Kojic Acid,,Arbutin, Phenoxyethanol, Glycyrrhetic Acid, Citric Acid, Lactic Acid, Phytic Acid, Sodium Cetearyl Sulfate, Sodium Lauryl Sulfate, Ascorbic Acid, Sodium, Lactate, Serine, Sorbitol,

# Tea-lactate, Urea, Ethylhexylglycerin, Sodium Chloride

**MELANO**out  
CREAM  
Skin Protectant  
30gr. e 1.06 fl.oz.

DRUG FACTS	
<b>ACTIVE INGREDIENTS</b> Allantoin 0,01% Glycerin 0,25%	<b>PURPOSE</b> skin protectant skin protectant
<b>KEEP OUT OF REACH OF BABIES AND CHILDREN</b> If product is swallowed, get medical help or contact a poison control center right away.	

**Inactive ingredient:** Water, Paraffinum Liquidum Mineral Water, Ethylhexyl Methoxycinnamate, Cetearyl Alcohol, Azelaic Acid, Salicylic Acid, Kojic Acid, Arbutin, Phenoxylethanol, Glycyrrhetic Acid, Citric Acid, Lactic Acid, Phytic Acid, Sodium Cetearyl Sulfate, Sodium Lauryl Sulfate, Ascorbic Acid, Sodium Lactate, Stearic, Sorbitol, Tea-lactate, Urea, Ethylhexylglycerin, Sodium Chloride.

**Warnings:**  
For external use only  
Do not 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:** cream formulated to attenuate and eliminate coetaneous spots of melanic origin located at epidermic level.

**Directions:** Cleanse the skin thoroughly before applying cream;  
Cover the entire affected area with a thin layer; First week apply three times daily (morning-afternoon-night); Second week apply two times daily (morning-night); Third week apply once a day, for a year.  
During summer it is recommended the application of the cream after sun exposure. If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

**KEEP OUT OF REACH OF BABIES AND CHILDREN**

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



- Cream formulated to attenuate and eliminate the coetaneous spot of melanic origin located at the epidermic level

## Melano Out Cream

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## Skin Protecting



## MELANO OUT CREAM

allantoin, glycerin cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70663-007
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALLANTOIN (UNII: 344S277G0Z) (ALLANTOIN - UNII:344S277G0Z)	ALLANTOIN	0.1 mg in 1 mL
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	0.25 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ)	1 mg in 1 mL
ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)	6 mg in 1 mL
WATER (UNII: 059QF0KO0R)	52.19 mg in 1 mL
AZELAIC ACID (UNII: F2VW3D43YT)	15 mg in 1 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.9 mg in 1 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.1 mg in 1 mL
MINERAL OIL (UNII: T5L8T28FGP)	13 mg in 1 mL
CETYL ALCOHOL (UNII: 936JST6JCN)	5.4 mg in 1 mL
KOJIC ACID (UNII: 6K23F1TT52)	1 mg in 1 mL
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	0.5 mg in 1 mL
LACTIC ACID (UNII: 33X04XA5AT)	0.5 mg in 1 mL
SODIUM LACTATE (UNII: TU7HW0W0QT)	0.25 mg in 1 mL
SORBITOL, L- (UNII: 01Q0586BG1)	0.25 mg in 1 mL
TRIETHANOLAMINE LACTATE (UNII: 064C51N81O)	0.25 mg in 1 mL
ARBUTIN (UNII: C5INA23HXF)	0.9 mg in 1 mL
ALLANTOIN GLYCYRRHETINIC ACID (UNII: H6FL381368)	0.6 mg in 1 mL
FYTIC ACID (UNII: 7IGF0S7R8I)	0.5 mg in 1 mL
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	0.3 mg in 1 mL
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	0.3 mg in 1 mL
ASCORBIC ACID (UNII: PQ6CK8PD0R)	0.25 mg in 1 mL
SERINE (UNII: 452VLY9402)	0.25 mg in 1 mL
HYDROXYETHYL UREA (UNII: MBQ7DDQ7AR)	0.25 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	0.05 mg in 1 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70663-007-02	30 in 1 BOX	12/17/2016	
1	NDC:70663-007-01	30 mL in 1 CONTAINER; 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	12/17/2016	

**Registrant - MESO SYSTEM S.A. (768263100)**

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
MESO SYSTEM S.A.		768263100	manufacture(70663-007)

Revised: 12/2016

MESO SYSTEM S.A.