

**HYDRAFACE- glycerin, dimethicone 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.*

-----

**HYDRAFACE CREAM**

**INACTIVE INGREDIENT**

Water, Stearyl Alcohol, Steareth-2, Isopropyl Myristate, Sodium Lactate, Serine, Imidazolidinyl Urea, Phenoxyethanol, Tea-Lactate

Tocopheryl Acetate, Lactic Acid, Ethylhexyl Methoxycinnamate, Mimosa Tenuiflora Extract, Decyl Oleate, Steareth-21, Sorbitol, Glyceryl Linoleate, Glyceryl Linolenate, Glyceryl Arachidonate, BHT, Ethylhexylglycerin, Retinyl Palmitate, Butylphenyl Methylpropional, D-limonene, Linalool, Parfum

P-CX-0003 hydraface 50ml - 8437008109039



50ml e 1.69 fl.oz

**DRUG FACTS**

<b>Active ingredients</b>	<b>Propose</b>
Dimethicone 0,1%	skin protectant
Glycerin 2%	skin protectant

**Uses**  
Hydrates deeply, offering elasticity, firmness and smoothness to the skin. Suitable for all kinds of dehydrated and devitalized skins, it helps to restore the optimal level of hydration and combats the free radicals preventing aging.

**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.  
When using this product do not get into eyes.  
Children under 6 months: ask a doctor.

**Directions**  
Clean and tonify the face and neck.  
Apply every day gently onto clean face and neck.  
Can be used in the morning and/or night.

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

**Inactive Ingredients**  
Aqua (Water), Stearyl Alcohol, Steareth-2, Isopropyl Myristate, Sodium Lactate, Serine, Imidazolidinyl Urea, Phenoxethanol, Tea-Lactate, Tocopheryl Acetate, Lactic Acid, Ethylhexyl Methoxycinnamate, Mimosa Tenuiflora Extract, Decyl Oleate, Steareth-21, Sorbitol, Glyceril Linoleate, Glyceril Linolenate, Glyceril Arachidonate, BHT, Ethylhexylglycerin, Retinyl Palmitate, Butylphenyl Methylpropional, D-limonene, Linalool, Parfum.

**Other information**  
Keep the product in a cool and dry place.

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

**Mesosystem**  
Calle Pau Claris, 97, 4<sup>a</sup>-1<sup>a</sup>  
08009 Barcelona  
Tel. + 34 902 105 458  
info@mesosystem.com  
www.mesosystem.com  
Made in Spain



**Hydraface  
Cream**

Skin Protectant

50ml e 1.69 fl.oz

El Hydraface es una crema hidratante y nutritiva indicada para todo el tipo de pieles deshidratadas y desvitalizadas que aumenta la elasticidad y firmeza de la piel. Ayuda a neutralizar los efectos adversos externos, funcionando como una barrera protectora frente a los radicales libres evitando el envejecimiento de la piel.

The Hydraface is a nutritive and moisturizing cream indicated for all types of dehydrated and devitalized skins that increases the skin elasticity and firmness. It helps to neutralize the adverse external effects, functioning as a protective barrier against free radicals preventing the skin aging.

O Hydraface é um creme hidratante e nutritivo indicado para todo o tipo de peles desidratadas e desvitalizadas que aumenta a elasticidade e firmeza da pele. Ajuda a neutralizar os efeitos adversos externos, funcionando como uma barreira protetora face aos radicais livres evitando o envelhecimento da pele.

Lote:

P-CX-0003

Codigo  
Barras

## **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 products keep out of eyes. Rinse with water to remove
- Children under 6 months: ask a doctor

## **WARNINGS**

### **For external use only.**

- When using this product do not get into eyes. Rinse with water to remove

### **Stop use and ask a Doctor if**

- Rash occurs

## **USES**

Hydrates deeply, offering elasticity, firmness and smoothness of the skin. Suitable for all kinds of dehydrated and devitalized skins. It helps to restore the optimum level of hydration and combats the free radicals preventing aging.

## **USES**

Hydrates deeply, offering elasticity, firmness and smoothness of the skin. Suitable for all kinds of dehydrated and devitalized skins. It helps to restore the optimum level of hydration and combats the free radicals preventing aging.

## **Keep out of reach of babies and childrens**

## **DIRECTIONS**

- Clean and tonify the face and the neck
- Apply every day gently onto clean face and neck
- Can be used in the morning and/or night.

## **QUESTIONS OR COMMENTS?**

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

## **ACTIVE INGREDIENT**

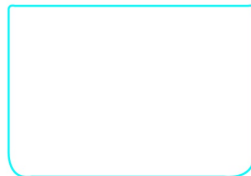
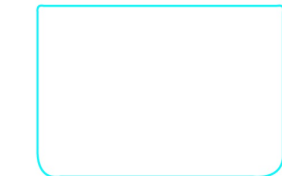
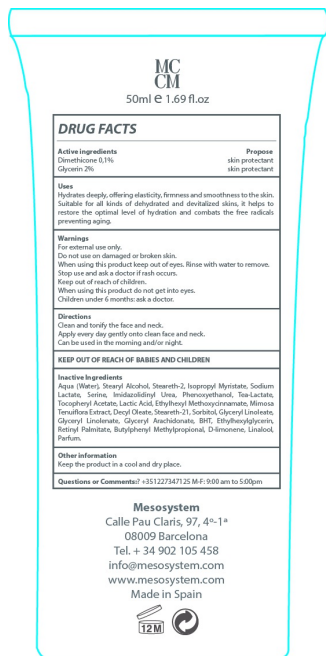
### **ACTIVE INGREDIENT PURPOSE**

Dimethicone 0.1%.....Skin Protectant

Glycerin 2%.....Skin Protectant

## **HYDRAFACE CREAM**

**Skin Protectant**



## HYDRAFACE

glycerin, dimethicone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70663-009
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLYCERIN (UNII: PDC6A3C0OX) (GLYCERIN - UNII:PDC6A3C0OX)	GLYCERIN	2 mg in 1 mL
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.1 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
GLYCERYL LINOLENATE (UNII: SGB6X4G86K)	0.1 mg in 1 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	0.9 mg in 1 mL
DECYL OLEATE (UNII: ZGR06DO97T)	0.1 mg in 1 mL
STEARETH-21 (UNII: 53J3F32P58)	0.1 mg in 1 mL
SORBITOL (UNII: 506T60A25R)	0.1 mg in 1 mL
STEARETH-2 (UNII: V56DFE46J5)	4 mg in 1 mL
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	4 mg in 1 mL
WATER (UNII: 059QF0KO0R)	76.65 mg in 1 mL
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	4 mg in 1 mL

<b>SODIUM LACTATE</b> (UNII: TU7HW0W0QT)	2 mg in 1 mL
<b>SERINE</b> (UNII: 452VLY9402)	2 mg in 1 mL
<b>IMIDUREA</b> (UNII: M629807ATL)	2 mg in 1 mL
<b>TRIETHANOLAMINE LACTATE</b> (UNII: 064C51N81O)	0.5 mg in 1 mL
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	0.3 mg in 1 mL
<b>LACTIC ACID</b> (UNII: 33X04XA5AT)	0.1 mg in 1 mL
<b>ETHYLHEXYL METHOXYCRYLENE</b> (UNII: S3KFG6Q5X8)	0.1 mg in 1 mL
<b>MIMOSA TENUIFLORA LEAF</b> (UNII: 46VJM10Q45)	0.1 mg in 1 mL
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	0.1 mg in 1 mL
<b>VITAMIN A PALMITATE</b> (UNII: 1D1K0N0VVC)	0.1 mg in 1 mL
<b>BUTYLPHENYL METHYLPROPIONAL</b> (UNII: T7540GJV69)	0.1 mg in 1 mL
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	0.1 mg in 1 mL
<b>LINALOOL, (+)-</b> (UNII: F4VNO44C09)	0.1 mg in 1 mL
<b>PEG-30 GLYCERYL LINOLEATE</b> (UNII: UPJ8VI2ZOC)	0.1 mg in 1 mL
<b>GLYCERYL ARACHIDONATE</b> (UNII: I4WS2B978B)	0.1 mg in 1 mL
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	0.1 mg in 1 mL
<b>PERFLUNAFENE</b> (UNII: 54A06VV62N)	0.05 mg in 1 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70663-009-02	50 in 1 CARTON	12/17/2016	
1	NDC:70663-009-01	50 mL in 1 BOTTLE; 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	

**Labeler** - MESO SYSTEMS A (768263100)

**Registrant** - Meso Systems S A (768263100)

### Establishment

Name	Address	ID/FEI	Business Operations
Meso Systems S A		768263100	manufacture(70663-009)

Revised: 12/2016

MESO SYSTEMS A