

**MANDELIC 2 PEEL GEL- allantoin gel**  
**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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**Mandelic 2 Peel Gel**

**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**

- Is for the skin that combines the coetaneus photo aging with acne and hyperpigmentation.
- Keep out of the reach of chuldren.
- In case of overdose get medical help or Contact a Poison Control Center right away.

**DIRECTIONS**

Apply the content with a brush. The time of application is 1 to 2 minutes. Rinse with cold water.

**QUESTIONS OR COMMENTS ?**

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

**ACTIVE INGREDIENTS**

**Active Ingredients Purpose**

Allantoin  
0.1%.....Skin  
Protectant

**Inactive Ingredients**

water, mandelic acid, hydroxyethyl ethylcellulose, alcohol denat, propanediol, phenoxyethanol, ethylhexylglycerin

Is for the skin that combines the coetaneus photo aging with acne and hyperpigmentation.

**Mandelic\_2 Peel Gel**

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**Skin Protecting**

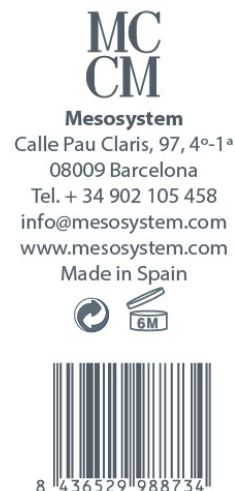
DRUG FACTS	
<b>Active ingredients</b> Allantoin 0.1%	<b>Propose</b> Skin protecting
<b>Uses</b> 1 for the skins that combine the coetaneous photo-aging with acne and hyperpigmentation.	
<b>Warnings</b> <ul style="list-style-type: none"> <li>• For external use only.</li> <li>• Do not used on damaged or broken skin;</li> <li>• Stop use and ask a doctor if rash occurs</li> <li>• Avoid the product from entering your eyes</li> <li>• Children under 6 months: ask the doctor</li> <li>• Keep out of reach of children. In case of overdose get medical help or Contact a Poison Control Center right away.</li> </ul>	
<b>Directions</b> Apply the content with a brush. The time of application is 1-2 minutes. Rinse with cold water.	
<b>KEEP OUT OF REACH OF BABIES AND CHILDREN</b>	
<b>Inactive Ingredients</b> Water, Mandelic Acid, Hydroxypropyl Methylcellulose, Alcohol Denat, Propylene Glycol, Phenoxyethanol, Ethylhexylglycerin.	
<b>Questions or Comments?</b> +351227347125 M-F: 9:00 am to 5:00pm	

# MC CM

## Mandelic\_2 Peel Gel

skin protecting

100ml e 3.5 fl. oz.



## MANDELIC 2 PEEL GEL

allantoin gel

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70663-006
<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

### Inactive Ingredients

Ingredient Name	Strength
HYDROXYETHYL ETHYLCELLULOSE (UNII: ZDN57Z154K)	2 mg in 1 mL
WATER (UNII: 059QF0K00R)	89.9 mg in 1 mL
MANDELIC ACID (UNII: NH496X0UJX)	4.5 mg in 1 mL
PHENOXYETHANOL (UNII: HIE492ZZ3T)	1 mg in 1 mL
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	0.1 mg in 1 mL
PROPANEDIOL (UNII: 5965N8W85T)	1 mg in 1 mL
ALCOHOL (UNII: 3K9958V90M)	1.5 mg in 1 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70663-006-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	12/14/2016	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	12/14/2016	

**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(70663-006)

Revised: 12/2016

MESO SYSTEM S.A.