

**SALICYLIC 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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**Salicylic 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**

**Mandelic\_2 Peel Gel**

**Skin Protecting**

| DRUG FACTS  |                                   |
|---|-----------------------------------|
| <b>Active ingredients</b><br>Allantoin 0.1%   | <b>Propose</b><br>Skin protecting |
| <b>Uses</b><br>1 for the skins that combine the coetaneous photo-aging with acne and hyperpigmentation.   |                                   |
| <b>Warnings</b><br><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><br>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><br>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  |                                   |

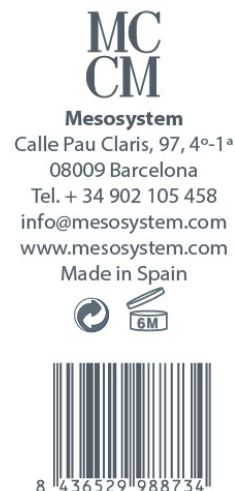
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## Mandelic\_2 Peel Gel

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skin protecting

100ml e 3.5 fl. oz.



## SALICYLIC 2 PEEL GEL

allanto in gel

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:70663-012 |
| <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: 059QF0KO0R)                       | 69.9 mg in 1 mL |
| SALICYLIC ACID (UNII: O414PZ4LPZ)              | 2 mg in 1 mL    |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)              | 0.9 mg in 1 mL  |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)          | 0.1 mg in 1 mL  |
| PROPANEDIOL (UNII: 5965N8W85T)                 | 10 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:70663-012-01 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 12/20/2017           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347                                  | 12/20/2017           |                    |

**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(70663-012) |

Revised: 11/2017

MESO SYSTEM S.A.