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|                         |                 |                  |         |                   |         |
|-------------------------|-----------------|------------------|---------|-------------------|---------|
| <b>Product:</b>         | L-Mesitran Soft | <b>GMDN code</b> | 47773   | <b>EMDN code</b>  | M040499 |
| <b>Available sizes:</b> | Product code    | Reference code   | Content | Container         |         |
|                         | LMS15           | 203.01           | 15g     | Tube              |         |
|                         | LMS20           | 204.01           | 20g     | Tube              |         |
|                         | LMS50           | 205.01           | 50g     | Tube              |         |
|                         | LMS250          | 208.01           | 250g    | Tube              |         |
|                         | LMS125J         | 206.01           | 125g    | Jar               |         |
|                         | LMS250J         | 207.01           | 250g    | Jar               |         |
|                         | LMS01S          | 201.10           | 0,9g    | Box of 10 sachets |         |

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| <b>Product Classification</b> | There are no active ingredients in L-Mesitran Soft, therefore L-Mesitran Soft is registered as a medical device Class IIb (Rule 4, Device Classification Rules according to Directive 93/42/EEC). |
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| <b>Ingredient</b>                            | <b>CAS number</b> | <b>European Pharmacopoeia</b> |              |
|--|-------------------|-------------------------------|--------------|
| Eco-honey                                    | 8028-66-8         | n/a                           |              |
| Medilan® (=low allergic lanolin)             | 8006-54-0         | Ph.Eur 7.4                    | 04/2012:0134 |
| Propylene glycol                             | 57-55-6           | Ph.Eur 7.0                    | 01/2008:0430 |
| PEG 4000 (Macrogols)                         | 25322-68-3        | Ph.Eur.7.0                    | 01/2008:1444 |
| Vit C ascorbic acid                          | 50-81-7           | Ph.Eur.7.0                    | 01/2011:0253 |
| Vitamin E (DL- $\alpha$ -tocopherol acetate) | 7695-91-2         | Ph.Eur.7.2                    | 07/2011:0439 |

**Product description**

L-Mesitran Soft is a gel that contains: 40% medical grade honey, medical grade hypoallergenic lanolin (Medilan®), propylene glycol, PEG 4000, and vitamins C & E. When the gel is in contact with the wound, fluid is drawn from the surrounding tissues through osmosis. By doing so, a moist wound healing environment is created. This environment stimulates the wound healing process: aids wound bed preparation by facilitating autolysis of necrotic and other devitalised material and promotes better epithelial cell migration.

- Due to the strong osmotic activity L-Mesitran Soft has antimicrobial properties.



- The gel will dilute gradually and can be removed easily as per local wound cleansing protocols.
- L-Mesitran Soft is a primary wound dressing that can be covered with most commonly used secondary dressings.
- The properties of the gel also help prevent the secondary dressing adhering to the wound bed.
- Due to the use of natural ingredients, each batch of gel may vary in colour (white - yellow - brown).
- The gel may contain sugar crystals, however this will not affect the effectiveness and/or application of the gel.

### Indications

- Chronic wounds.
- Pressure ulcers (Stage I-IV).
- Venous stasis ulcers.
- Fungating wounds (to help deodorise and/or debride).
- Colonised acute wounds.
- Surgical wounds.
- Postoperative wounds.
- Traumatic wounds (superficial wounds, cuts).
- Small burn and laser wounds (superficial and partial thickness burns).

### Contraindications

L-Mesitran Soft gel is not indicated for:

- Third degree burns.
- Patients with a known sensitivity to honey or any other component parts.
- Dirty, infected and heavily exuding wounds (should first be cleansed).
- Deep narrow cavities.

### Precautions

- Due to the dressing's low pH, some patients may notice slight transient stinging upon application of the dressing. If stinging persists and cannot be managed with an analgesic, remove dressing, cleanse area, and discontinue use.
- During initial use of the dressing (depending on wound exudate levels, interstitial fluid, and edema surrounding the wound), the dressing's high osmolarity may contribute to increased exudate. This can be managed by adjusting the frequency of dressing change according to the level of exudate.
- Bacterial colonisation of chronic wounds is always present and is not a contraindication for using L-Mesitran Soft.
- During the healing process, due to autolytic debridement it is common for non-viable tissue to be removed from the wound resulting in an initial increase in wound size. Although an initial increase in size may be attributed to the normal removal of non-viable tissue, consult a healthcare professional if the wound continues to grow larger after the first few dressing changes.
- After removing the dressing, if some material remains and is not easily removed, soak with sterile saline or water until it is removed without difficulty.

- Consult a healthcare professional if you see signs of infection, which can include increased redness, increased pain, increased wound drainage, increased skin irritation, and changes in wound color and/or odor.
- When opening and applying the gel from a new container, ensure that the new container is not damaged or previously opened.
- L-Mesitran® Soft is for use by a single patient only. The container may be re-used with the same patient.
- Always close the container after use.

**Hazards**

No hazards are known to date.

**Storage precautions**

**Store at room temperature 5°-25°C / 41° - 77°F. Store dry. Do not freeze.**

L-Mesitran® Soft is a natural product and may become liquid under varying temperatures. If this is expected to be a problem, then the product may be placed in a fridge prior to use. The storage conditions are detailed on the product cartons and tubes as symbols.



**Shelf life**

3 years (real time data).

**Date of introduction on the EU market**

April 2004.

**Approval QA representative**

| Signature   | Date              | Company stamp  |
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|  | <p>14-01-2022</p> |  |