



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 118701 Paul Hartmann Pty Ltd - Exudate-absorbent dressing, non-gel

**ARTG entry for** Medical Device Included Class IIb  
**Sponsor** Paul Hartmann Pty Ltd  
**Postal Address** PO Box 943, NORTH RYDE BC, NSW, 1670  
Australia  
**ARTG Start Date** 21/04/2005  
**Product Category** Medical Device Class IIb  
**Status** Active  
**Approval Area** Medical Devices

### Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.  
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### Manufacturers

| Name             | Address   |
|------------------|---|
| Paul Hartmann AG | Paul-Hartmann-strasse 12<br>D89522 HEIDENHEIM, , D-89522<br>Germany |

### Products

#### 1 . Exudate-absorbent dressing, non-gel

|                         |  |                       |            |
|-------------------------|--|-----------------------|------------|
| <b>Product Type</b>     | Single Device Product  | <b>Effective Date</b> | 21/04/2005 |
| <b>GMDN</b>             | 44970 Exudate-absorbent dressing, non-gel  |                       |            |
| <b>Intended Purpose</b> | For use with superficial, severely or moderately secreting wounds during the cleansing stage and for building up the granulation tissue (conditioning) in the following application areas:<br>- chronically problematic wounds such as leg ulcers (Ulcus cruris) of various genesis (not infected)<br>- Decubitus or pressure sores(not infected)<br>- Burns up to 2nd degree (2a) |                       |            |

### Specific Conditions

No Specific Conditions included on Record

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