

Vliwaktiv®

Absorbent Activated Charcoal Dressing, sterile

REF 20254, 20255

March 2009

Translation: MI / P. Kellmann

1. Composition of the product

Vliwaktiv® Absorbent Activated Charcoal Dressings consists of:

- | | |
|----------------------------|---|
| - nonwoven envelope: | viscose and polyamide |
| - cellulose material: | cellulose |
| - clothing protection: | polypropylene |
| - Activated charcoal felt: | Activated charcoal fibres |
| - hotmelt adhesive: | synthetic polymer with resins and waxes |

This product data sheet covers the following items:

REF 20254 Vliwaktiv® Absorbent Activated Charcoal Dressing, sterile
10 x 10 cm

REF 20255 Vliwaktiv® Absorbent Activated Charcoal Dressing, sterile
10 x 20 cm

2. Packaging, structure and composition

2.1 Unit container

- peel pouch (cellulose)

2.2 Shelf container

- folding cardboard box (cellulose)

2.3 Transit container

- corrugated cardboard box (cellulose)

3. **Manufacture**

Vliwaktiv® Absorbent Activated Charcoal Dressings are produced according to specification in hygienic conditions and packed as described in the relevant packaging specification.

The product is sterilized by steam according to DIN EN ISO 17665-1.

4. **Description**

Vliwaktiv® Absorbent Activated Charcoal Dressings consist of a nonwoven envelope which does not stick to the wound, an activated charcoal felt, several layers of cellulose, and a nonwoven clothing protection.

The absorbent dressing is individually packed and sterile and available in sizes 10 x 10 cm and 10 x 20 cm.

5. **Properties**

Vliwaktiv® Absorbent Activated Charcoal Dressings are rectangular absorbent dressings which bind odours and absorb bacteria.

6. **Intended purpose**

Vliwaktiv® Absorbent Activated Charcoal Dressings are intended to be used in the treatment of malodorous wounds such as leg ulcers, decubital ulcers, anal fistulae, etc.

7. **Medical device classification**

Vliwaktiv® Absorbent Activated Charcoal Dressings are a medical device of Class Is in terms of Rule 4.

(Council Directive 93/42/EEC concerning medical devices, Annex IX)

8. **Biological evaluation and biocompatibility (DIN EN ISO 10993)**

According to the clinical assessment and risk analysis performed, the medical/ pharmacological safety of Vliwaktiv® Absorbent Activated Charcoal Dressings is guaranteed if the product is used appropriately and for the purposes intended.

The starting materials (viscose, polyamide, polypropylene, cellulose, and activated charcoal fibres) are considered harmless and indifferent from the pharmacological/ toxicological point of view if the product is used as intended.

On the finished product the hotmelt adhesive used has no direct contact with the patient's skin and is thus of secondary significance in this statement.

To date this company has received no notification of incidents involving this Lohmann & Rauscher product, neither has there been need for a recall for reasons of quality.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical device Vliwaktiv[®] Absorbent Activated Charcoal Dressing and that it is designed, manufactured and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

9. Stability

Stored appropriately Vliwaktiv[®] Absorbent Activated Charcoal Dressings have a shelf life of 5 years.

10. Disposal

The user is advised to observe current legislation, norms and guidelines, regulating the disposal of medical refuse.

Packaging materials must also be disposed of in compliance with applicable national requirements.

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signed by
Dr. Martin Abel
(Medical & Regulatory Affairs)