# Product Data Sheet

| | |
|---|---|
| **1.0 Name of the product** | **Leukoplast® compress cotton gauze (T17, non sterile)** |
| **2.0 Product description** | |
| **2.1 Description** | Leukoplast® compress cotton gauze are non-sterile, white absorbent cotton gauze type 17 for single use. |
| **2.2 Intended purpose** | Leukoplast® compress cotton gauze is intended for skin and wound cleansing, absorption of secretion/exudates. As mechanical barrier it is suitable as a primary or secondary dressing in order to cover a wound and to provide cushioning. The device is for short-term use.<br>The use of device is not restricted to a specific patient population.<br>Intended users are healthcare professionals. |
| **2.3 Instructions for use** | No IFU is required for this kind of product due to the low risk to user.<br>All necessary information for safe use is available on labelling |
| **2.4 Warnings and precautions for use** | The following symbols are used on every packaging level:<br>• Do not re-use<br>• Nonsterile<br> |
| **2.5 Contraindications** | There are no known contraindications |
| **2.6 Transport Precautions** | Dry, clean and without exposure to direct sunlight |
| **2.7 Duration of application** | For Short-term use. |

**2.8 Composition**

| Designation | Description | % of final product |
|---|---|---|
| Compress | White gauze, 100% Cotton, Type 17 | 100 |

## 2.9 Product range

| Product code | Size | Ply | Gauzes per Paper bag | Paper bags per Shipper | UoM |
|---|---|---|---|---|---|
| 71234-00 | 5 x 5 cm / 2 x 2 in | 8 | 100 | 30 | 100 x 30 = 3000 |
| 71234-04 | 5 x 5 cm / 2 x 2 in | 12 | 100 | 30 | 100 x 30 = 3000 |
| 71234-08 | 5 x 5 cm / 2 x 2 in | 16 | 100 | 30 | 100 x 30 = 3000 |
| 71234-01 | 7.5 x7.5 cm/ 3 x 3 in | 8 | 100 | 20 | 100 x 20 = 200 |
| 71234-05 | 7.5 x7.5 cm/ 3 x 3 in | 12 | 100 | 20 | 100 x 20 = 200 |
| 71234-09 | 7.5 x7.5 cm/ 3 x 3 in | 16 | 100 | 20 | 100 x 20 = 200 |
| 71234-02 | 10 x 10 cm / 4 x 4 in | 8 | 100 | 10 | 100 x 10 = 1000 |
| 71234-06 | 10 x 10 cm / 4 x 4 in | 12 | 100 | 10 | 100 x 10 = 1000 |
| 71234-10 | 10 x 10 cm / 4 x 4 in | 16 | 100 | 10 | 100 x 10 = 1000 |
| 71234-03 | 10 x 20 cm / 4 x 8 in | 8 | 100 | 10 | 100 x 10 = 1000 |
| 71234-07 | 10 x 20 cm / 4 x 8 in | 12 | 100 | 10 | 100 x 10 = 1000 |
| 71234-11 | 10 x 20 cm / 4 x 8 in | 16 | 100 | 10 | 100 x 10 = 1000 |

## 2.10 Sizing Chart

See 2.9

## 2.11 Storage conditions

Dry, clean and without exposure to direct sunlight

## 2.12 Shelf life/ Storage time

5 years

## 2.13 Sterilization

Not applicable

## 2.14 Key quality parameters

| Characteristic | Target |
|---|---|
| Absorption | >7g/g |

## 3.0 Chemical substances of special concern to Essity

Essity has defined chemical substances that are of special concern and are subject to specific restrictions. A reference to the list of substances can be found in Annex A2 via the following link www.essity.com/gss

Deviations are covered in 3.1 Components.

## 3.1 Components

Raw materials used in product formulation

| Substance | Included in formulation |
|---|---|
| natural rubber Latex | No |
| Lanolin and its derivatives | No |
| Colophony | No |
| Colophony derivatives | No |
| Bisphenol A (BPA) | No |
| Polyvinylchloride (PVC) | No |
| Methylmethacrylate | No |
| Butylacrylate | No |
| Microplastics (<5 mm) | No |
| Nanoparticles | No |
| Fragrance/parfum | No |
| Antibiotics | No |
| Triclosan | No |
| Chlorhexidine | No |
| Polyhexanide | No |

Raw materials used in the packaging

| Substance | Included in formulation |
|---|---|
| Polyvinylchloride (PVC) | No |
| Natural rubber latex | No |
| Recycled material | Partly in shipper and folding box |

Raw materials used in the product formulation and in the packaging may contain small amounts of the substances listed above and not marked as included in formulation as well as amounts of other substances not listed above. As trace level analysis is not performed for each batch BSN medical GmbH cannot provide proof of absence.

# History

| Version / Date | Page / Item | Description of Change |
|---|---|---|
| 01 / 01.2023 | All | Set up new document |
| 02 / 03.2023 | 1.0 Name of the product | Name corrected |
| | 2.9 Product range | The table has been redesigned |