

Sorbalgon®/Sorbalgon® T



Spec.-No.: D 9.2200a

Department: SM-PDW

Date: 2010-11-29

1. General Product Description

Sorbalgon®, a conformable, non-medicated dressing made of calcium alginate fibres which forms a hydrophilic non adherent gel in contact with the sodium salts contained in blood and wound exudate; the gel fills the wound cavity and creates a favourable healing condition, drawing bacteria from the wound and keeping them inside the gel.

Sorbalgon® T is a non-medicated conformable ribbon.

Sorbalgon® / Sorbalgon® T carries the CE mark according to EU directive 93/42/EEC for medical devices. The product is classified as a class IIb medical device.

A conformity assessment has been performed for Sorbalgon® / Sorbalgon® T and it has been shown to be in compliance with all applicable requirements of the above mentioned directive.

The safe use and effectiveness of Sorbalgon® / Sorbalgon® T, therefore, is ensured if the product is used in line with the intended purpose.

2. Application / Indication

May be used in the treatment of external wounds of any type; especially suitable for the treatment of bleeding or secreting wounds, since the gel-forming properties promote the wound healing process, e.g. venous leg ulcers, pressure sores, abscesses, furuncles, burns, difficult wounds following accident or tumour surgery.

3. Presentations

Sorbalgon® dressings, sterile, individually sealed

dimensions: 5 x 5 cm
 10 x 10 cm
 10 x 20 cm

Sorbalgon® T ribbon with crepe paper insert, sterile, individually sealed

dimensions: 1g / 30 cm
 2g / 30 cm

4. Product Characteristics

Material composition:

min. 99 % Alginate fibres	complies with the requirements of the British Pharmacopoeia, current edition, monograph "Alginate Fibres", classification "Type I— fibre";
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5. Product Requirements**Sorbalgon**basis weight: min. 120 g/m²absorbency after 30 Min.: min. 12 g/100 cm²**Sorbalgon T**Weight
1g min. 0,9 g

2g min. 1,8 g

Absorbency after 30 min. min. 6 g/g


6. Labelling

Lot-No. with 3-digit code:

LOT

 e.g.: Sorbalgon S593
Sorbalgon T R156

Expiry date:

e.g.:  2015 – 12
year – month

Shelf life: 5 years

Sorbalgon®/Sorbalgon®T



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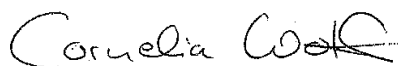
7. Packaging

Sorbalgon® / Sorbalgon® T individual sealed in peel-pouches, packed into folding box; transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

Date: 29th November 2010

PAUL HARTMANN AG
Product Development SM-PDW

p.p.

A handwritten signature in black ink that reads "Cornelia Wolf".

Cornelia Wolf