

## Coverflex®Fast



Spec.-No.: D 9.4051  
Department: COM-DGM  
Date: 2018-05-30

### 1. General Product Description

Coverflex®fast is a seamless round knitted tubular bandage mainly made of viscose. It is right-left knitted and has inlayed elastic threads covered with PA yarn in every second row.

CoverflexFast is a non-sterile permanently elastic tubular bandage for use on skin of humans.

It is for single-use and can be used by lay persons and healthcare professionals in clinical and home environment.

The product is classified as a class I medical device.

### 2. Application / Indication

Coverflex fast can be used

by lay persons and healthcare professionals

- as a secondary fixation dressing for application in combination with primary dressings for the treatment of acute and chronic wounds.

under supervision of healthcare professionals

- as a moist dressing in dermatology when moistened for short-term (< 30 days) treatment in the acute phase of atopic eczema in a special moisture and ointment therapy for application in combination with liquids, ointments and cremes.

- as a dry dressing in dermatology for long-term treatment in the chronic phase of atopic eczema for application in combination with externa such as ointments, cremes, powder, tincture/lotion, paste.

- as an inner lining for long-term prevention of skin irritation for application in combination with compression, zinc paste, support, cast, adhesive and cohesive bandages.

### 3. Presentations

Coverflex®fast is available in 10 m rolls.

Available Sizes:

Size	Color	Application	Nominal Width	Size Recommendation
Size 1	Red	for children's arms, elbows and feet and adult's toes and fingers	3,5 cm	8 – 12 cm
Size 2	Green	adult's hands, arms and feet and children's legs and arms	5 cm	12 – 25 cm
Size 3	Blue	adult's arms and legs and children's heads and legs	7,5 cm	20 – 45 cm
Size 4	Yellow	adult's arms, legs and heads, children's heads and trunks	10,75 cm	35 – 65 cm
Size 5	Beige	adult's trunks	17,5 cm	56 – 120 cm

### 4. Product Characteristics

Material composition:

91% Viscose

5% Polyamide

4% Polyurethane

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### 5. Product Requirements

Construction:	right-left, inlayed elastic threads in every second row
Elongation CD:	> 230%
Residual elongation after multi-cycle stress:	< 15 %
Residual elongation after stress with 1,2 kg for 60 min:	≤ 10 %
Ability to stay wet (in laboratory test):	≥ 0,5 h
Amount of ointment going through product (in defined laboratory conditions):	< 1,0 g
Amount of loops per 10 cm:	200 ± 30
Amount of courses per 10 cm:	80 ± 10
Weight per area:	> 100 g/cm <sup>2</sup>

Sterilizing capability: Steam sterilization at 134°C for 10 min with saturated steam at 134 °C for 10 min (according to DIN EN ISO 17665 with validated processes).

### 6. Labelling

Lot-No. with 9-digit code:

Lot.-No.	3	999	01	00	1
Explanation	[3 = 2013]	[999 – 000]	Internal Code		
Definition	Last figure	Serial production order			

Expiry date: Year – Month – Day  
 Example: 2020 – 03 - 01  
 Shelf Life: 5 years

### 7. Packaging

Coverflex®Fast 10 m rolls are packed individually in dispensers. The dispensers are packed in transport cartons, sealed with adhesives tapes and packed onto euro pallets.

Date: 30<sup>th</sup> May 2018

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i.A.



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