Zetuvit® Plus, sterile

General Product Description

Zetuvit Plus is a sterile superabsorbent dressing used on superficial, moderately to severely exuding wounds. The absorbent core absorbs and binds exudate.
Zetuvit Plus is a combined superabsorbent dressing which consists of four layers of different materials. On the wound side, the product features a soft, white, hydrophilic nonwoven (viscose and polyamide). The inner dressing core consists of soft cellulose fluff blended with liquid-retaining polyacrylate polymers. This absorbent core is enclosed in a thin nonwoven fabric that evenly distributes the liquid. On the side facing away from the wound, the product features a green layer of polypropylene nonwoven, which is water-repellent but permeable to air and allows for gas exchange.

Intended Purpose

Single use sterile superabsorbent dressing for long-term treatment of injured skin, acute and chronic, with moderate to high levels of exudate. It is used on adults only, by healthcare professionals in clinical or homecare environments and can be combined with local antiseptics, primary and secondary dressings.

Application/Indication

Zetuvit Plus rapidly absorbs exudate and binds it within the absorbent core. Exudate removal eliminates inhibitory factors from the wound, e.g. proteases.
The increased absorption capacity of Zetuvit Plus reduces the required frequency of dressing changes. This promotes wound rest and provides additional protection against contamination.
Apart from its absorbent quality, Zetuvit Plus also has a padding effect.

Zetuvit Plus is suitable for the treatment of superficial, moderately to severely exuding acute wounds (traumatic wounds, post-operative wounds, lymphatic wounds, arterial leg ulcers) and chronic wounds (decubitus/pressure sores, venous or mixed leg ulcers, tumour wounds). Zetuvit Plus can be used under compression bandages.

Reference Numbers

Packaging	10x10	10x20	15x20	20x25	20x40
P10	413 710	413 711	413 712	413 713	413 715*
	413 110*	413 111*	413 112*	413 113*	

*The peel pack of the dressing is not intentionally made with natural rubber latex.

Contra-Indications and Undesirable Side Effects, Warnings

Do not use Zetuvit Plus on dry wounds or on exposed bones, muscles or tendons.
Do not use Zetuvit Plus in case of hypersensitivity to any of its components.

Cautions and precautions

Do not cut the dressing.

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Medical assessment of the wound condition and the causes of wound-healing impairment is necessary before treating wounds with an impaired healing tendency. Treatment with Zetuvit Plus cannot replace a causal treatment of the wound-healing impairment.
If there are clinical signs of infection, the infection needs to be controlled with appropriate treatment before this dressing can be used. In all cases, follow the established clinical protocol. In the absence of available data supporting the use of this dressing on sensitive population groups such as infants, children, pregnant or nursing women, and in the absence of data to the contrary, on these population groups this dressing should be used with caution following a clinician's recommendation.
For dressings which are packed in paper-paper peel packs: The sealed seam of the peel pack contains natural rubber latex, which may cause allergic reactions!

Sterile Device

Ethylene oxide sterilization.
Do not use if package is damaged.

Single Use Device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product Disposal

In order to minimize the risk of potential infection hazards, or environmental pollution, disposable components of the medical device should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards. Dispose of the medical device with household waste.

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Product Performance Characteristics

Product				
Property	**Test method**	**Unit**	**Requirements**	**Test results**
Free absorption	EN 13726-1 chap 3.2	g/100cm²	140-220	160
Sealing strength of primary packaging (paper-paper peelpouch)	MO00CTL 0022	N/15mm	min. 0.8	min. 1.1
Sealing strength of primary packaging (paper-film blister)	MO66CTL 0347	N/15mm	min. 1	min. 1.7

All data refer to sterile products.

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Labelling

Lot-No. with 9+6 Digit Code

e.g.:

LOT	X	XXX	XX	XX	X	XX	X	X	XX
	year	internal order number	charge of sterilization	plant	control digit	week	day	shift	machine

Manufacturing Date

e.g.:	2020	-	07	-	18
	year		month		day

Use-by-Date

e.g.:	2025	-	07	-	01
	year		month		day

Shelf Life: 3 years

Medical Device

MD

Unique Device Identification (UDI)

UDI

Single Sterile Barrier System

Single sterile barrier system

Latest Date of Revision: 2020-06-04