Zetuvit®/Gipvit® (Pansement absorbant stérile)/Zetuvit® E, sterile

General Product Description

Zetuvit/Gipvit(Pansement absorbant stérile)/Zetuvit E is a sterile single use absorbent pad, made of smooth cellulose fibers (fluff); covered on the backside by an hydrophobic nonwoven, being water repellent and permeable to air; together surrounded by a cellulosic tissue layer for secretion distribution; the whole is wrapped in a non-adherent and hydrophilic nonwoven. The backside is characterized by a blue coloured thread.
Gipvit (Pansement absorbant stérile), distributed by Giphar, is exactly the same dressing as Zetuvit but differs in its labelling and is only sold in France.
Zetuvit/Zetuvit E in bulk are sold in sterile care kits with other components.

Intended Purpose

Zetuvit/Gipvit (Pansement absorbant stérile)/Zetuvit E is a sterile single use absorbent dressing used for the treatment of exuding wounds, acute or chronic, and for upholstering and cushioning of wounds.

Application/Indication

Zetuvit/Gipvit (Pansement absorbant stérile)/Zetuvit E is an absorbent dressing for covering wounds and ensuring mechanical protection (for upholstering and cushioning).
Use for the treatment of exuding wounds, acute and chronic.
Use as a mechanical barrier and for absorption of body fluids (e.g. exudate, blood, pus)

Reference Numbers

Packaging		10x10	10x20	13.5x25	15x20	15x25	20x20	20x25	20x40
bulk	Zetuvit	019 701							
	Zetuvit E	019 710	019 702		019 969				
P5	Zetuvit								413 704
	Zetuvit E		413 779						
P10	Zetuvit	413 651	413 652	413 705	413 653			413 654	
	Zetuvit E	413 784				413 773			413 776
	Gipvit (Pansement absorbant stérile)	413 670	413 671		413 672			413 673	
P15	Zetuvit						413 703		
	Zetuvit E						413 774	413 775	
P25	Zetuvit	413 701 413 708	413 702 413 709		413 772				
	Zetuvit E	413 770	413 771						

Contraindications and Undesirable Side Effects, Warnings

No contraindication

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Cautions and precautions

Zetuvit/Gipvit (Pansement absorbant stérile)/Zetuvit E are packed in paper-paper peelpouch: the sealed seam of peelpouch contains natural rubber latex, which may cause allergic reactions. Except size 20x40cm which is packed in paper-film blister and the sealed seam of the blister does not contain natural rubber latex.

Sterile Device

EO sterilization for care kits (Zetuvit/Zetuvit E in bulk)
Steam sterilization for the other products: 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

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of Zetuvit/Gipvit(Pansement absorbant stérile)/Zetuvit E should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

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	50-100	60
Sealing strength of primary packaging (paper-paper peelpouch)	MO00CTL 0022	N/15mm	min. 0.8	min. 1.7
Sealing strength of primary packaging (paper-film blister)	MO66CTL 0349	N/15mm	min. 1	min. 2.2

All data refer to sterile products.

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

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Manufacturing Date

e.g.:		2019	-	07	-	18
		year		month		day

Use-by-Date

e.g.:		2024	-	07	-	01
		year		month		day

Shelf Life: 5 years

Medical Device

MD

Unique Device Identification (UDI)

UDI

Single Sterile Barrier System

Single sterile barrier system

Latest Date of Revision: 2020-03-01