

# Zetuvit®/Zetuvit® E, unsterile

## General Product Description

Zetuvit/Zetuvit E is an unsterile 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.

## Intended Purpose

Zetuvit/ Zetuvit E is an unsterile single use absorbent dressing used as a mechanical protection for upholstery and cushioning of acute and chronic wounds.

## Application/Indication

Zetuvit/Zetuvit E is an absorbent dressing for secondary wound covering and mechanical protection (for upholstery and cushioning).

Wound protection in case of acute and chronic wound.

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
P30	Zetuvit	413 801	413 802	413 805			413 803		413 804
	Zetuvit E								413 866
P50	Zetuvit E	413 860	413 861		413 862	413 863	413 864	413 865	

## Contraindications and Undesirable Side Effects, Warnings

No contraindication

## 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/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.

# Zetuvit<sup>®</sup>/Zetuvit<sup>®</sup> E, unsterile

## Product Performance Characteristics

Product				
Property	Test method	Unit	Requirements	Test results
Free absorption	EN 13726-1 chap 3.2	g/100cm <sup>2</sup>	50-100	60

## Labelling

### Lot-No. with 9+6 Digit Code

e.g.:



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.:



2019	-	07	-	18
year		month		day

### Use-by-Date

e.g.:



2024	-	07	-	01
year		month		day

Shelf Life: 5 years

### Medical Device



### Unique Device Identification (UDI)



Latest Date of Revision: 2020-02-25