

Technical Data Sheet

Dermaplast[®] / Cosmos[®] EFFECT

Corns/Blisters/Heel/Cut



Specifications: P 7.6108

Department: RD-PHSA

Date: 04/07/2017

CHANGE CONTROL REPORT

Page /Edition	Replaces Page/Edition	Reason for Change
1-2-3 from 25/11/2013	-----	New Technical Data Sheet
1-2-3 from 04/07/2017	1-2-3 from 25/11/2013	Updated Technical Data Sheet

Department	Date	Signature
PHSA-RD, Product Developer, Gemma Galván	04/07/2017	

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1. General Product Description:

DermaPlast® / Cosmos® EFFECT Corns/Blisters/Heel/Cut wound plasters are hypoallergenic adhesive wound plasters made hydrocolloid material.

DermaPlast® / Cosmos® EFFECT Corns/Blisters/Heel/Cut carries the CE mark according to EU Directive 93/42/EEC for medical devices. The product is classified as a class **Ila** medical device.

A conformity assessment has been performed for DermaPlast® / Cosmos® EFFECT Corns/Blisters/Heel/Cut and it has been shown to be in compliance with all the applicable requirements of the above-mentioned Directive. The safe use and effectiveness of DermaPlast® / Cosmos® EFFECT Corns/Blisters/Heel/Cut is ensured if the product is used in line with the intended purpose.

2. Application / Indication:

Protection as a mechanical barrier and/or treatment and absorption of exudate in case of blisters, corns, cuts (small, non-bleeding or slightly bleeding, dry and clean wound).

3. Presentation:

Code	Description	Assortment	Dimensions of Plastic / Folding box
536008	Dermaplast East Corn	60x18 mm (8st)	Plastic box: 72,85 x 18,25 x 114,8mm + eurohanger
536038	Dermaplast East Blister	19 x 55 mm (6st)	Plastic box: 72,85 x 18,25 x 114,8mm + eurohanger
536018	Dermaplast East Heel	76 x 45 mm (5st)	Plastic box: 72,85 x 18,25 x 114,8mm + eurohanger
536540	Dermaplast West Corn	17x40 mm (7st)	Plastic box: 72,85 x 18,25 x 114,8mm + eurohanger
536340	Dermaplast West Blister Small	19 x 55 mm (6st)	Plastic box: 72,85 x 18,25 x 114,8mm + eurohanger
536140	Dermaplast West Heel	76 x 45 mm (6st)	Plastic box: 72,85 x 18,25 x 114,8mm + eurohanger
536003	Cosmos Corn	17x40 mm (6st)	Folding box: 75 x 15 x 105 mm + 25 mm eurohanger
536033	Cosmos Small Blister	19 x 55 mm (6st)	Folding box: 75 x 15 x 105 mm + 25 mm eurohanger
536013	Cosmos Heel	76 x 45 mm (5st)	Folding box: 75 x 15 x 105 mm + 25 mm eurohanger

4. Product Characteristics:

Material composition:

1	Backing material	Double Hydrocolloid.
2	Protector paper	Silicone paper, white.

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5. Product requirements:

Static absorption Hydro:	3150 ± 1150 g/m ² /24h	TM00 0145
Peel adhesion (90°)*:	5,3 ± 2,5 N/25mm	TM00 0090-04
Bioburden:	≤ 100 cfu/g Absence of E.Coli, St. aureus, Ps.aeruginosa, Enterobacteria.	PH501/001 PH503/001

*These values are valid for the original coated roll (final product might have different values)

6. Labelling:

Lot-No. with 9-digit code:

LOT	X	XXX	XX	12	X
	year	No.of production order of the article	Week of the year	Plant number	Control digit

Shelf Life: The shelf life is 3 years.

Example expiry date:



2016 – 06
Year – Month

7. Packaging:

DermaPlast®/Cosmos® EFFECT Corns/Blisters/Heels/Cut are packed into folding boxes, transport carton acc. DIN, sealed with adhesive tapes, packed onto europallet.

➤ **Identification of each packaging :**

With 1 specific label with information of the product (Batch number, name of the product, expiry date, trade mark, number of boxes, code of the product).

DermaPlast®/ Cosmos® EFFECT Corns/Blisters/Heels/Cut should be stored in cool and dry conditions in a good ventilated area.