

Technical Data Sheet

Dermaplast[®] / Cosmos[®] EFFECT

“Cold sore patch”



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 Cold sore patch wound plasters are hypoallergenic adhesive wound plasters made of ultra thin hydrocolloide. DermaPlast® / Cosmos® EFFECT Cold sore patch are Skin-friendly, soft and pleasant, method of treating cold sores on the lips or nose, helps to relieve pain and itching, helps to prevent crusting and scar formation.

DermaPlast® / Cosmos® EFFECT Cold sore patch 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 Cold sore patch and it has been show to be in compliance with all the applicable requirements of the above-mentioned Directive. The safe use and effectiveness of DermaPlast® / Cosmos® EFFECT Cold sore patch is ensured if the product is used in line with the intended purpose.

2. Application / Indication:

Protection, treatment and absorption of exudates in case of cold sores.

3. Presentation:

Code	Description	Assortment	Dimensions of Plastic box
536085	Dermaplast East	17x12 mm (16st)	72,85 x 18,25 x 114,8mm + eurohanger
536840	Dermaplast West	17x12 mm (16st)	72,85 x 18,25 x 114,8mm + eurohanger
536083	Cosmos	17x12 mm (16st)	72,85 x 18,25 x 114,8mm + eurohanger

4. Product Characteristics:

Material composition:

1	Backing material	Ultra thin hydrocolloide
2	Protector paper	Silicone paper, white / blue

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5. Product requirements:

Static absorption Hydro:	> 1000 g/m ²	TM00 0145
Peel adhesion on SS (90°)*:	3,5 ± 1 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:



2019 – 06
Year – Month

7. Packaging:

DermaPlast® / Cosmos® EFFECT Cold sore patch 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 Cold sore patch should be stored in cool and dry conditions in a good ventilated area.