

PHARtulle

10 x 10 cm

Sterile paraffin dressing

Medical device

Wound care

Presentation

PHARtulle - Sterile dressing in the form of a support impregnated with a neutral base composed of vaseline jelly and paraffin, packaged in a sterile envelope.

Product code	Presentation/dimensions/ quantity	No. of pieces/box
3401.0.4384523-3	Vaseline and paraffin based dressing 10 cm x 10 cm	10

Composition

- Support made of cotton lattice
- Protective sheets
- Impregnation: neuter base made of Vaseline and Paraffin

Properties

- On the wound, the dressing assure a contact interface that creates the favorable local microclimate for the cicatrization process (cicatrization in moist environment)
- It is not adherent (to tissues) to the wound; removal is easy and atraumatic
- Easy to apply in the case of wounds found in difficult areas (e.g. anatomical folds, mucocutaneous junctions, etc.)

Indications

- Local treatment of acute wounds: burns, excoriations, superficial traumatic wounds
- Local treatment of bedsores and chronic vascular ulcers

Contra-indications

There are no contraindications.

Instructions for use

- The wound must be cleaned with physiological serum, before each use of the paraffin dressing
- In case of previous usage of an antiseptically, wash the wound with physiological serum before applying the paraffin dressing
- The paraffin dressing is applied in a single layer directly on the wound, after removal of protective sheets
- This dressing can be cut according with the size and/or form of the wound, using a sterile instrument
- Cover the wound with a secondary compress (for absorption of secretions) and fix it with an extensible or fix bandage, adhesive or not
- The dressing is replaced every day or every 2 days, depending of the wound healing process

Precautions for use

- If there are signs of local infection, treatment can be continued with the physician's approval

Additional precautions

- The presence of a deep wound does not involve the use of multiple dressings at the same time
- Single-use product; do not re-sterilize
- Sterile only if the packaging is not damaged
- Storage:
 - Horizontally
 - Protected from humidity and sunshine
 - Temperature: max. 35°C.

Undesirable side effects

- None known

Warnings

- Products are single use medical devices, do not re-use! Otherwise it may appear: irritation /contamination/ infection of wound and/or skin
- The product is exclusively for external use; ingestion of the impregnation base may cause stomach problems
- Do not use the product if the packaging is damaged
- The products should not be further used after the expiration date printed on the box
- The products should be kept away from children and pets. Penetration in the wound of hair or stains from pets can cause wound contamination
- For people with mental disabilities, the products should only be used under supervision of a mentally healthy person

Note

Any serious incident that has occurred in relation to TAISSIS CONCEPT S.R.L. products should be reported to TAISSIS CONCEPT S.R.L. and the competent authority of the Member State in which the user and/or patient is established.

SYMBOL	SIGNIFICANCE	SYMBOL	SIGNIFICANCE	SYMBOL	SIGNIFICANCE
	Single use product		Keep away from sunlight!		Means that it is absolutely necessary for the user to read the leaflet before starting the utilization of the product
	The product is sterilized with Gamma radiations Do not resterilize!		Compliance with MDD 93/42/EEC		Expiry date
	Do not use if the package is damaged!		Single sterile barrier system		Unique Device Identifier
	Keep dry!		Non-sterile protective packaging with sterile barrier system inside		Medical device
	Storage at a temperature up to 35°C		Medical device		Symbol for warning regarding throwing the pack to the trash bin
			Product reference (code)		Manufacturer
			Product lot number		

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Medical device

Regulatory status: IIa Class medical devices according to MDD 93/42/ EEC

