

# Calmogel®

Medical device  
First aid for burns

## Presentation form

Sterile impregnated dressing/sterile bandage for burns of a support from polyurethane foam impregnated with hydrogel, packed in individual envelope.

| Product code | Presentation form/dimensions                                       | UDI-DI        |
|--------------|--|---------------|
| C3.100GM     | Sterile impregnated dressing for burns, 10 cm x 10 cm              | 5944729007009 |
| C3.200GM     | Sterile impregnated dressing for burns, 20 cm x 20 cm              | 5944729006965 |
| C3.420GM     | Sterile impregnated dressing for burns, 20 cm x 40 cm              | 5944729007016 |
| C3.640GM     | Sterile impregnated dressing for burns, 40 cm x 40 cm              | 5944729006958 |
| C3.M640GM    | Sterile impregnated dressing for burns, 40 cm x 60 cm, Facial Mask | 5944729007023 |
| C3.1612GM    | Sterile impregnated dressing for burns, 120 cm x 160 cm            | 5944729007047 |
| C3DGM        | Sterile bandage for burns, 2.5 cm x 50 cm, Finger                  | 5944729006941 |
| C3MGM        | Sterile bandage for burns, 5 cm x 100 cm, Hand                     | 5944729006941 |

## Composition

### Composition of Calmogel® – Sterile impregnated dressing/sterile bandage for burns

- Support made of polyurethane (foam)
- The hydrogel contains: Glycerin, Propylene Glycol, Carbopol, Sodium Hydroxide 10%, Menthol 0.05%, Purified water

## Clinical benefits

- Reduces pain and decrease the edema
- Minimize the burn evolution
- The cooling of the burn with water is not necessary anymore, because the progressive evaporation of the water molecules from the hydrogel allows the absorption of calories by heat transfer. This evaporation lasts about 45 minutes
- Ensure the favorable microclimate for burn healing
- Limit the risk of hypothermia; placing the Calmogel® dressing/bandage directly over the affected area cools the burn and avoids rapid cooling on other body surface area as does showering or hosing the patient
- Sterile impregnated dressings/sterile bandages for burns do not adhere on the tissue and can be removed without pain and trauma
- Easy to use; fresh smell of menthol

## Performance characteristics

- Using the products, helps to reduce:
  - the healing and treatment time
  - the treatment costs

## Indications

- First aid for thermal burns, including sunburns and chemical burns, I, II and III degree

## Contra-Indications

- DO NOT USE the sterile impregnated dressing/sterile bandages for burns if the patients are allergic to any of the hydrogel components

## Instructions for use

### Thermal burns, including sunburns:

- Wash your hands thoroughly
- Open the envelope and remove the dressing/bandage. Gently lay the dressing/bandage on the site of the burn, ensuring that the whole of the wound is covered
- Carefully squeeze the rest of the gel from the envelope over the top of the dressing/bandage
- Wrap the dressing/bandage for burns to keep it in place with a non-absorbent bandage, such as a cohesive bandage or conforming bandage and fix it with an adhesive tape (if necessary). Take care to ensure that pressure is not applied to the area when bandaging
- The dressing/bandage for burns must be kept on the burned area for 30-45 minutes while the patient is driven to a hospital unit

### Chemical burns

- It is recommended to use only after limiting chemical contact with tissues and decreasing chemical concentration
- After water jetting for 20 to 30 minutes, it is possible to neutralize the chemical and continue to give first aid as a thermal burn

## Precautions for use

- If there are signs of local infection, treatment can be continued with the physician's approval
- Products are exclusively for external use
- When first aid is given in the case of chemical burns, chemical neutralizing agents are used only with the consent of the physician

## Additional precautions

- The products should not be further used after the expiration date
- The products should be kept away from children
- Single-use product; DO NOT re-sterilize
- Sterile only if the packaging is not damaged
- Storage:
  - Protected from humidity and sunshine
  - Temperature: max. 35°C.

## Undesirable side-effects

- None known

## Warnings

- The use of products is restricted only to practitioners (doctors, paramedics, first aid personnel)
- Products are single use medical devices, do not re-use! Otherwise it may appear: irritation/ contamination/ infection of burn and/or skin
- The product is exclusively for external use; ingestion of the hydrogel 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
- The products should be kept away from children and pets. Penetration in the burn of hair or stains from pets can cause burn contamination
- Care should be taken to avoid hypothermia especially in those patients who are most at risk; infants, elderly and those with large surface area burns. It is recommended that hydrogel dressings are not used on children and the elderly if it covers more than 10% of the Total Body Surface Area (TBSA), and for adults no more than 20% TBSA. In these situations, follow your protocols in force (e.g. wrap the patient in an emergency foil thermal blanket over their wet dressings, so as to hold the evaporation to a minimum)

## 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



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| Symbol | Significance  | Symbol | Significance  |
|--------|---|--------|---|
|        | Single use product  |        | 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                     |        | Expiry date   |
|        | Single sterile barrier system                                       |        | Date of manufacture   |
|        | Non-sterile protective packaging with sterile barrier system inside |        | Keep dry!   |
|        | Do not resterilize!   |        | Keep away from sunlight!  |
|        | Do not use if the package is damaged!                               |        | Storage at a temperature up to 35°C   |
|        | Medical device  |        | Symbol for warning regarding throwing the pack to the trash bin   |
|        | Product reference (code)  |        | Fragile. Handle with care!  |
|        | Product lot number  |        | Manufacturer  |
|        | Unique Device Identifier  |        | Compliance with Regulation (EU) 2017/745  |



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according to Regulation (EU) 2017/745

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