

TECHNICAL SHEET

Name of the medical device	CINESTEAM[®], secondary absorbent anti-odour dressing
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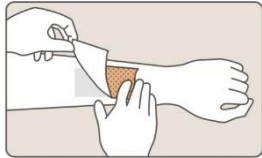
1. Legal manufacturer contact information	
1.1	Name: CEMAG CARE
1.2	<p>Address: 55, rue de Turbigo 75003 Paris France</p> <p>Phone number : +33 1 58 28 16 83 Email : contact@cinesteamcare.com Website : www.cinesteamcare.fr</p>
1.3	<p>Post-market surveillance responsible: Manon Exposito</p> <p>Phone number : +33 1 86 22 02 11 Fax : +33 1 73 79 35 54 Email : pharmacovigilance@cemagcare.com</p>

2. Device information	
2.1	Commercial name: CINESTEAM [®]
2.2	SRN (Single registration number) : FR-MF-000003779
2.3	Basic UDI-DI: 3665851M0402999K
2.4	<p>Classification: Class I medical device according to Rule 4 of annex VIII of Regulation 2017/745</p> <p>First Launch date in EU: 07th February 2020</p> <p>Conformity Assessment Route: EC conformity declaration according to annex IV and V of Regulation 2017/745</p>
2.5	Indications: secondary absorbent anti-odour dressing for malodorous wounds

2.6	<p>Device description: Cinesteam® is a secondary dressing for bad smells reductions and exudates absorption. It is composed of an absorbent core and a sachet containing cinnamon powder. The cinnamon adsorbs malodorous volatile organic components (VOCs) released by chronic wounds and masks the potential residual bad smells while emitting a natural spice odour.</p>						
2.7	<p>Catalogue reference:</p> <table border="1"> <thead> <tr> <th>Product code</th> <th>Dimensions</th> <th>Packaging</th> </tr> </thead> <tbody> <tr> <td>112010</td> <td>Cinesteam® 11 cm x 19 cm</td> <td>Box of 12 dressings</td> </tr> </tbody> </table> <p>Dressings are packed individually in a PA/PE pouch.</p>	Product code	Dimensions	Packaging	112010	Cinesteam® 11 cm x 19 cm	Box of 12 dressings
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112010	Cinesteam® 11 cm x 19 cm	Box of 12 dressings					
2.8	<p>Composition of the device: Polyethylene, polyester, polypropylene and cinnamon.</p>						

4. Storage conditions	
4.1	<p>Normal storage conditions: room temperature Cinesteam® has to be stored protected from light and moisture. Cinesteam® must be transported and stored in flat position. Cinesteam® should not be used after the expiration date indicated on the box/dressing label.</p>

5. Security	
5.1	Technical security: Cinesteam® is a secondary dressing which should not be in direct contact with the patient.
5.2	Biological security (if relevant): NA

6. Conditions of use	
6.1	<p>For full instructions, please refer to the Instructions For Use (IFU) included in the box and in annex at the end of the document. Cinesteam® must be applied over a primary wound contact layer and should not be applied directly to the wound</p> <p>Cinesteam® application:</p> <ol style="list-style-type: none"> 1. Open and remove Cinesteam from its pouch. 2. Apply the white face Cinesteam® on top of the primary dressing so that it covers it entirely. 3. Secure Cinesteam® in place using adhesive tape or a retaining bandage.  <p>Cinesteam® renewal: Remove smoothly Cinesteam®. The frequency of dressing change must be adapted to the wound care protocol in place. Cinesteam® can be left in place as long as its absorption and odour masking capacities are satisfactory (1 to 7 days). Frequency of change should be dependent on the level of exudate.</p>
6.2	<p>Precautions:</p> <ul style="list-style-type: none"> • Do not use Cinesteam® as a primary dressing.

	<ul style="list-style-type: none"> Do not cut Cinesteam® because this could induce cinnamon leakage. Cinesteam® should not be used if its primary packaging is open or damaged or if the dressing itself is torn. Do not use Cinesteam® together with an active charcoal dressing, which may decrease its odour masking ability Do not cover Cinesteam® with an occlusive fastening material or dressing. Do not eat the cinnamon of Cinesteam®. Do not bathe or shower when wearing Cinesteam®. Do not immerse Cinesteam® in water. Keep out of the reach of children.
6.3	<p>Contraindications</p> <p>Cinesteam® should not be used on patients with known sensitivity to any of its components, in particular cinnamon.</p>

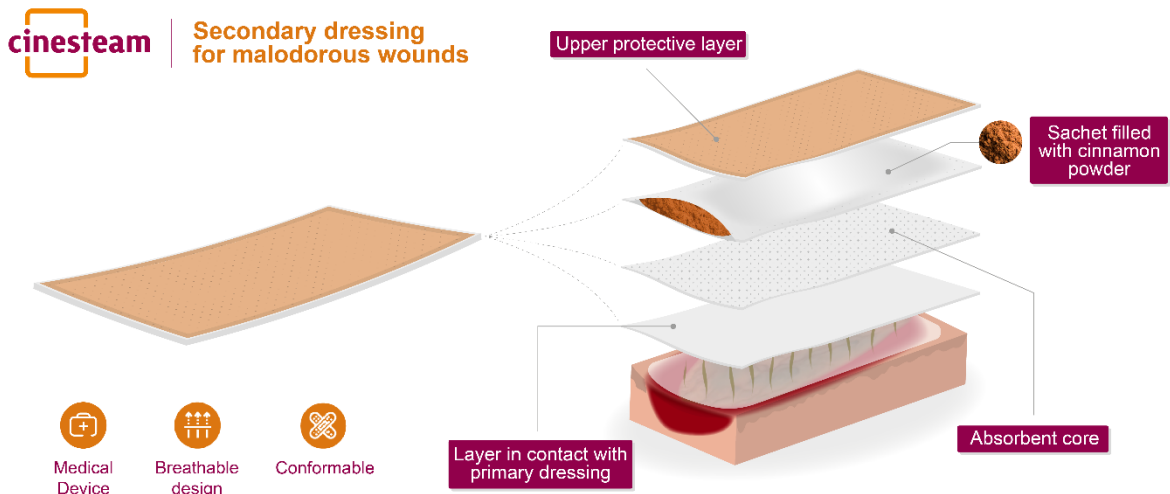
7. Product complementary information

Refer to IFU

8. Annex list

8.1 Design of the dressing

8.2 IFU



EN INSTRUCTIONS FOR USE - Cinesteam® - Secondary anti-odour absorbent dressing

DESCRIPTION

Cinesteam® is a non-adhesive secondary dressing designed to absorb exudates and eliminate unpleasant odours. It consists of an absorbent layer together with a sachet containing cinnamon. Composition: polyethylene, polyester, polypropylene and cinnamon.

Cinnamon adsorbs unpleasant-smelling volatile compounds emanating from the wound and masks residual odours with spice natural fragrance.

INDICATIONS

Cinesteam® is a secondary dressing indicated for the management of malodorous wounds.

CONTRAINDICATIONS

Cinesteam® should not be used on patients with known sensitivity to any of its components, in particular cinnamon.

DIRECTIONS

Cinesteam® should be applied on top of an appropriate primary dressing (it is not intended to be in direct contact with the wound). The absorbent layer (white face) should be applied facing the wound, over the primary dressing.

Application of Cinesteam®

1. Select the size of Cinesteam® that covers the primary dressing. If necessary, more than one dressing Cinesteam® may be used.
2. Remove Cinesteam® from its primary packaging and apply it directly onto the primary dressing.
3. Keep Cinesteam® in place with any suitable medical material.

Changing Cinesteam®

Gently peel off Cinesteam®.

Cinesteam® can be left in place as long as its absorption and odour masking capacities are satisfactory (1 to 7 days). Frequency of change should be dependent on the level of exudate.

PRECAUTIONS

Do not use Cinesteam® as a primary dressing.

Do not cut Cinesteam® because this could cause cinnamon leakage.

Cinesteam® should not be used if its primary packaging is open or damaged or if the dressing itself is torn.

Do not use Cinesteam® together with an active charcoal dressing, which may impair its odour masking ability.

Do not cover Cinesteam® with an occlusive fastening material or dressing.

Do not eat the cinnamon of Cinesteam®.

Do not bathe or shower when wearing Cinesteam®.

Do not immerse Cinesteam® in water.

Keep out of the reach of children.


Report any serious incidents which occur in connection with Cinesteam® to Cemag Care and to the healthcare competent authority of your country.


If you have any further questions, ask your doctor, pharmacist or nurse.

AVAILABLE SIZES


Cinesteam® is available in:
• 11 x 19 cm


STORAGE AND SPECIFIC INSTRUCTIONS

 Ship and store flat.


 Keep away from sunlight.


 Keep dry.

 Do not re-use.


 Apply the white face towards the wound.



 Do not cut the dressing.


 Read the package leaflet before use.

 Product code

 Batch number

 Use by date

 CE Mark

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Date of last revision: 17/06/2022