

Änderungsnummer / Change Master: C2135



Objektverknüpfungen / Object Links:

JBX 40010461 000 04 Actimove Physiopack

Dokumentenstückliste / Document Structure:

JBN DIN EN ISO 13485:2016-08 000 Medical devices - Quality management sys
JBN DIN EN ISO 13485 BER.2017 000 Medical devices - Quality management sys
JBN ISO 13485 PRACTICAL GUIDE 000 2016 -Medical devices -A practical guide
JBN ISO 13485:2016-03 000 Medical devices - Quality management sys

Status	Responsible	Date
IE in Erstellung	DEHANKG	01.07.2019
AF Freigabeanford.	DEHANKG	04.07.2019
FR freigegeben	DEHANAN	04.07.2019

Product Safety Data Sheet


Document will not be automatically updated

1.0 Name of the product	Actimove[®] Physiopack[®]
2.0 Product description	
2.1 Description	<p>Actimove[®] Physiopack[®] is a re-useable gel pack for external hot or cold application. The gel can be prepared for cold application by cooling (freezer or refrigerator) or by heating (hot water or microwave). Actimove[®] Physiopack[®] is applied on the area to be treated with a cloth or towel in between the gel pack and the skin. Whatever medical condition is addressed cooling or warming is typically applied for 20-30 minutes. It can be used by medical staff or by the patient himself and is designed to be re-usable. The product is a class 1 medical device according to MDD 93/42, Canadian MDR, and US FDA.</p>
2.2 Characteristics	<ul style="list-style-type: none"> - Can be used hot or cold for up to 30 minutes - Maintains conformability during cold application / Always remains flexible when hot or cold - Product fits perfectly around limbs for an even cold or heat distribution. - Re-useable - Isotherm boxes of appropriate sizes can keep gel pack at functional hot or cold temperature for approximately 6 hours. - Soft pack without hard edges for a comfortable application - Pack is easy to clean after use - Can be disinfected
2.3 Intended use	<p>Actimove[®] Physiopack[®] is intended for external application of heat or cold.</p> <p>Application fields for cooling include:</p> <ul style="list-style-type: none"> - Acute soft tissue injuries - Local inflammations (e.g. tendinitis, bursitis) - Chronic diseases (e.g. osteoarthritis, rheumatoid arthritis) - Muscle spasms - Rehabilitation after soft tissue injuries <p>Applications for heating include:</p> <ul style="list-style-type: none"> - Muscular pain - Subacute inflammations (including arthritis) - Soft tissue stiffness

2.4 Instructions for use	Yes
2.5 CE-class GMDN - code	CE class I, Rule 1 GMDN Code 37240
2.6 Duration of application / Period of use	One day to several days, depending on the status of the medical conditions
2.7 Composition	<p>Actimove Physiopack® is manufactured from a blue gel in a soft white plastic bag.</p> <p>The gel consists of water, refrigerant, thickener, preservatives, neutralising agent and food dye.</p> <p>min. 65 g (+ 10%) for 7,5 x 10cm min. 400 g (+ 10%) for 12 x 29cm min. 500 g (+ 10%) for 16 x 26 cm</p> <p>Plastic made of laminated PE/PA/PE.</p>
2.8 Latex in product and packaging material	Product and packaging are not made with natural rubber latex.
2.9 Phthalate in product and packaging material	Product composition: No phthalate content Packaging material: No phthalate content
2.10 Controls	Visual characteristics (e.g. colour/ appearance, packaging/labelling)

2.11 Product range			
Product code	Size	Per folding box	Per shipper
Actimove [®] Physiopack [®]			
72075-14	7.5 x 10 cm	4 HOT/COLD PACKS IN A BOX and 1 leaflet	12
72075-15	7.5 x 10 cm	4 HOT/COLD PACKS IN A BOX and 1 leaflet	12
72075-16	12 x 29 cm	1 HOT/COLD PACK IN A BOX and 1 leaflet	12
72075-17	16 x 26 cm	1 HOT/COLD PACK IN A BOX and 1 leaflet	12
72075-18	7.5 x 10 cm	CASE OF 80 HOT/COLD PACKS and 1 leaflet	80
72075-19	7.5 x 10 cm	CASE OF 80 HOT/COLD PACKS and 1 leaflet	80
72075-20	12 x 29 cm	CASE OF 25 HOT/COLD PACKS and 1 leaflet	25
72075-21	16 x 26 cm	CASE OF 20 HOT/COLD PACKS and 1 leaflet	20
2.12 Storage conditions	Dry and Clean, no specific requirements for product in folding boxes or shipper case. Products without folding box or shipper needs sun protection.		
2.13 Shelf life/Storage time	3 years		
2.14 Sterilization	Product is not sterile		

3.0 Safety information	
3.1 Warnings and precautions for use	<ul style="list-style-type: none">- Do not use on skin. Always place a cloth, towel or wrap between the Actimove[®] Physiopack[®] and your skin.- Cooling and warming should be limited to 20-30 minutes.- Do not swallow the gel, in case of accidental ingestion consult a physician.- Supervise use with children.
3.2 Flammable or combustible properties	Combustible solid
3.3 Health Hazards	No health hazard is anticipated during normal handling of this product.
3.4 Contraindications	<ul style="list-style-type: none">- Do not apply a cold Actimove[®] Physiopack[®] in case of impaired circulation, Raynaud's disease, cryoglobulinaemia, paroxysmal cold haemoglobinuria, and cold urticaria.- Do not apply a hot Actimove[®] Physiopack[®] in case of impaired circulation, neoplasm, sensory problems, acute trauma, bleeding, acute inflammation, and acute oedema.
3.5 Fire Hazard and Emergency Action	In case of fire any standard fire extinguisher may be used
3.6 Transport Precautions	Not applicable
3.7 First Aid	<ul style="list-style-type: none">a) Inhalation: Not applicableb) Contact with skin: Not applicablec) Contact with eyes: Not applicabled) Ingestion: Not applicable
3.7 Disposal	Controlled incineration / landfill according to local environmental health guidelines.

	<p align="center">BSN documentation system JBM 40011953 000 02 PSDS Physiopack</p>	<p>Released: 04.07.19-... Seite 6 von 6</p>
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4.0 General information	
4.1 Name, address and telephone number of legal manufacturer	BSN medical GmbH an Essity company Quickbornstrasse 24 20253 Hamburg GERMANY Tel. ++ 49 40 4909-909 Fax ++ 49 40 4909-6666
4.2 Certificates for Quality Management	Certificate acc. EN ISO 13485 (notified body: Dekra) available

History

Version/Date	Page /Item	Description of Change
01/10.12.2009	Set up new document	
02/01.07.2019	All pages	General revision, because of new product of another manufacturer

