

Instructions for use

Product name

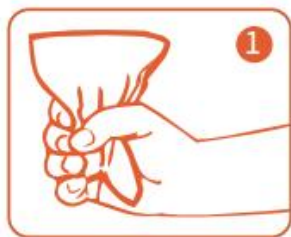
Hot packs

Specification

No.	Model	Specification			
		Outer packing Size	Net weight/pcs	Weight of Magnesium sulfate powder	Weight of Water Bag
1	H153229D	15.3×22.9cm	230g±5g	90g±2.5g	140g±2.5g
2	H127153B	12.7×15.3cm	100g±5g	40g±2.5g	60g±2.5g
3	H150170C	15×17cm	150g±5g	60g±2.5g	90g±2.5g
4	H150170D	15×17cm	200g±5g	80g±2.5g	120g±2.5g
5	H130150B	13×15cm	100g±5g	40g±2.5g	60g±2.5g
6	H108330B	10.8×33cm	110g±5g	40g±2.5g	70g±2.5g
7	H110145B	11×14.5cm	100g±5g	40g±2.5g	60g±2.5g

Use Method

1. Locate inner pouch. Squeeze firmly to rupture inner fluid pouch.
2. Shake briefly to mix contents.
3. Wrap the Hot Pack in 4-5 layers of towels or clothes to avoid direct contact with the skin.
4. Apply to affected area, the recommended hot compress time is 15 ~ 20 minutes.



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Temperature performance

Maximum temperature	The maximum temperature measured from the beginning to the end of heating.	≤ 65°C
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Temperature rise time	The time required from product activated to temperature rise to 40°C.	≤ 2min
Temperature guarantee time	The total amount of time that the heating temperature is maintained above 40°C.	≥30 min

Intended use

Hot Pack is used for providing localised pain relief for low back.

Intended patient population

The Hot pack is applied to adults and children over 12 years old who require treatment for lower back pain.

The hot pack shall not be applied to following patients:

- Children under 12 years old;
- Sensory impaired or unconscious patients;
- Pregnant women;
- Woman experiences abnormal bleeding or other serious symptoms (such as severe pain or fever) during her menstrual period;
- Patients situations mentioned in the contraindications.

Intended user

Hot pack shall only be used by adults who can read and understand the instruction manual.

Indications

- Low back pain;

Contraindications

- Acute abdominal disease
- Preliminary stage of soft tissue bruise or sprain
- Skin eczema/allergic dermatitis
- Healing Wounds
- Sensation Impaired
- Cognitive or communication deficits that preclude reporting of pain
- Over areas of acute inflammation
- Fragile skin
- Vascular insufficiency or vascular disease
- Hemorrhage or potential hemorrhage
- Over areas of known malignancy

Undesirable side-effects

Avoid pressing the hot pack on skin directly, which may cause rash and burn. Most time this symptom is transient and typically resolve within a few hours. If the symptom is not alleviate exceed one day, please turn to medical attention.

Intended clinical benefits

Providing localised pain relief for low back.

**Warnings**

- For external use only.
- Read instructions before using.
- Check the packaging bag without leakage and product within expiry date before using.
- Do not apply if skin is impaired in any way.
- Do not use on infants. Supervise children during use.
- Keep out of reach of children.
- Harmful swallowed. If accidentally swallowed, contact poison control center or physicians immediately.
- If bag breaks and fluid comes in contact with skin or eyes, flush with water immediately and call a physician.
- Individuals with circulatory problems should consult a physician before using this product.
- Shall pay attention to the elderly, children and people with communication barriers.

**Cautions**

- Peak temperature may reach 65°C once activated.
- Always wrap a towel or cloth before applying. 400g/m² microfiber toweling is recommended for wrapping.
- If the pack feels too warm or if there are significant skin color changes, more layers of toweling should be added or the hot pack should be removed.
- Prior to use, store at room temperature.
- Patients should not lie with their full body weight on top of a hot pack.
- Do not puncture outer bag.
- Do not reuse by heating.

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

Storage/Transportation conditions

At a temperature between 4°C and 35°C and avoid direct sunlight.

Shelf life

1 year.

Importer

Name

Address [Note: the specific importer information will be printed in the printed version of IFU]

Manufacturer

JIANGSU INTCO MEDICAL PRODUCTS CO., LTD.

No. 298 Yandunshan Road, Zhenjiang New District, 212132 Jiangsu P.R. China

EU Authorized Representative

MedNet EC-REP C IIb GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

Effective Date:

2025-9-13

Revision:

A/3

Contact information

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Email: sunguihua@intco.com

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and to your national authority.

The contacts of national competent authorities (Vigilance Contact Points) and further information can be found on the following European Commission website:
https://ec.europa.eu/growth/sectors/medical-devices/contacts_en.

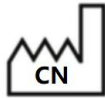


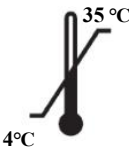
<https://www.intcomedical.com/web/upload/2025/09/17/175809027280624r8pa.pdf>

Website: www.intcomedical.com

eIFU can be queried on the website.

Symbol

No.	Symbol	Meaning
1		Date of Manufacture Country of Manufacture
2		Use-by date
3		Manufacturer
4		EU authorized representative
5		Batch Code
6		CE Marking, and Notified Body Code
7		Caution
8		Do not reuse
9		Do not use if package is damaged
10		Catalogue number
11		Medical device
12		Importer

No.	Symbol	Meaning
13		Unique device identifier
14		Model number
15		Keep away from sunlight
16		Temperature limit
17		Keep dry
18		Consult electronic instructions for use

