

FIELD SAFETY NOTICE

MYMEDIC INNOVATION SDN BHD



No	Product	Type	Brand
1	Ultrasound Gel (Bottle) 260g	Non-Sterile	Mymedic Innovation Sdn bhd
2	Ultrasound Gel 5kg	Non-Sterile	Mymedic Innovation Sdn bhd
3	ECG Gel (Bottle) 260g	Non-Sterile	Mymedic Innovation Sdn bhd
4	ECG Gel 5kg	Non-Sterile	Mymedic Innovation Sdn bhd

INSTRUCTIONS FOR USE:

Description of Ultrasound Gel

Mymedic Ultrasound Gel is a conductive medium that enables a tight bond between the skin and probe, letting the electric pulse transmits directly to the tissues beneath and to the parts that need to be imaged. It formulated to act as a coupling agent and reduce static. It is micro bubble free, not irritant, bacteriostatic, alcohol free, non-greasy, water soluble, salt free, does not stain the probe, clean easily and odorless.

Description of ECG Gel

Mymedic ECG Gel is a conductive medium that enables a tight bond between the skin and electrodes, letting the electric pulse transmits directly to the tissues beneath. It is micro bubble free, not irritant, bacteriostatic, alcohol free, non-greasy, water soluble, salt free, does not stain and odorless.

INDICATIONS FOR USE

Mymedic Ultrasound Gel and Mymedic ECG Gel can be used on intact, unbroken skin and on all patients in facilities where cross contamination is of minimal concern. Refill containers and refillable dispensers (product numbers USG90402 and ECG90404) are for use on low-risk patients and procedures in non-acute care facilities. Follow the enclosed instructions for use or your facility's protocol, if it is different.

CONTRAINDICATIONS

Mymedic Ultrasound Gel, in multi-use packaging, is for external use only and should not be used in:

- Any invasive procedures in which a device is passed through the tissue, e.g. needle aspiration, needle localization, tissue biopsy, or other surgical procedures.
- Any procedure on or near broken skin, such as fresh surgical site or an open wound
- Patients with an immunodeficiency or on immunosuppressive therapy.
- Any neonates or critically ill pediatric patients.
- Mucous membranes
- Critically ill patients or patients in contact-, airborne- or droplettransmission-based precautions.

Mymedic ECG Gel, in multi-use packaging, is for external use only and should not be used in:

- Defibrillation procedures.

STORAGE CONDITIONS

Store in a cool dry place (10°C - 40°C). Store away from direct sunlight. Store in a clean environment.

MYMEDIC INNOVATION SDN BHD (757536-K)

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WARNINGS AND PRECAUTIONS

Discard product if package is damaged or evidence of contamination is present. To avoid contamination, tips of containers should not come into contact with patient, staff or instruments. Apply Ultrasound / ECG Gel to transducer / electrode surface, and not directly on to the patient. After the procedure is completed, completely remove excess gel from the patient's skin. Disinfect the area if required.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer **Immediately**.

DIRECTION FOR HANDLING / REFILLING DISPENSER BOTTLES

- a) Clean your hands and put on your gloves before using the product.
- b) Disinfect any medical equipments that is used with the product with alcohol or a hospital-grade disinfectant, such as Disinfectant Wipes
- c) Reusable bottle should be **washed, rinsed, disinfect** and thoroughly **dried** before being refilled.

260g:

- i. Only use sanitized instruments to open the bottle.
- ii. To avoid contamination, dispenser tip of bottle should not come into contact with patient, staff or instruments.
- iii. Immediately close the bottle cap after using the product.
- iv. The product should be marked with the date used and then **discarded after 28 days**.
- v. Discard product if bottle is damaged or evidence of contamination is present.

5kg:

- i. Refilling process must be done in a clean and hygienic environment.
- ii. Reusable bottle should be **washed, rinsed, disinfect** and thoroughly **dried** before being refilled.
- iii. Discard any excess gel before capping.
- iv. The product should be marked with the date used and then **discarded after 28 days**.
- v. Discard product if bottle is damaged or evidence of contamination is present.

d) Only refill product into corresponding labeled dispenser, and mark it with lot number. Reusable bottles should be marked with the date filled and then **discarded after 28 days**.

e) Cracked or damaged bottles should be discarded immediately. Remaining gel should be disposed prior to refilling.

f) When not in use **keep lid closed**

FOR MORE REFERENCE



- 1. Field Safety Notice
- 2. <https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7148a3-H.pdf>

 Catalogue Number



Do Not Use if Package is Damage



Caution



Do Not Reuse



Batch Code



Non Sterile



Protect From Sunlight



Temperature Limit



Date Manufactured



Non Polyvinyl chloride



Refer Instruction



Date of Expiry



Use Litter Bin



Manufacturer

Revision No : 2
Issue Date : 5 Jun 2024

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