

HELIUM- helium gas
Medical-technical Gases, Inc.

Helium

HELIUM, COMPRESSED USP

UN1046

RX Only. WARNING: Administration of Helium may be hazardous or contraindicated. For use only by or under the supervision of a licensed practitioner who is experienced in the use and administration of Helium and is familiar with the indications, effects, dosages, methods, and frequency and duration of administration, and with the hazards, contraindications and side effects, and the precautions to be taken.

WARNING: CONTAINS GAS UNDER PRESSURE; MAY EXPLODE IF HEATED. MAY DISPLACE OXYGEN AND CAUSE RAPID SUFFOCATION. Do not handle until all safety precautions have been read and understood. Use and store only outdoors or in a well-ventilated place. Use a back flow preventive device in the piping. Use only with equipment rated for cylinder pressure. Close valve after each use and when empty. Protect from sunlight when ambient temperature exceeds 52 C (125 F). Read and follow the Safety Data Sheet (SDS) before use. FIRST AID: IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention. CAS: 7440-59-7 DO NOT REMOVE THIS PRODUCT LABEL

MEDICAL-TECHNICAL GASES, INC.

8 EXECUTIVE PARK DRIVE NORTH BILLERICA, MA 01862

TEL. 800 FINE GAS FAX (781) 395-9098 www.medtechgases.com

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HELIUM

helium gas

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:10736-020 |
| Route of Administration | RESPIRATORY (INHALATION) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| HELIUM (UNII: 206GF3GB41) (HELIUM - UNII:206GF3GB41) | HELIUM | 990 mL in 1 L |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:10736-020-01 | 623 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/07/2021 | |
| 2 | NDC:10736-020-02 | 5689 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/07/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| NDA | NDA205864 | 01/07/2021 | |

Labeler - Medical-technical Gases, Inc. (019481373)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------------|----------------|---------------|----------------------------|
| Medical-technical Gases, Inc. | | 019481373 | manufacture(10736-020) |

Revised: 10/2023

Medical-technical Gases, Inc.