

HELIUM OXYGEN MIXTURE- helium oxygen mixture gas
Medical-technical Gases, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Helium Oxygen Mixture

COMPRESSED GAS, N.O.S.

(80% HELIUM, USP, 20% OXYGEN, USP)

UN 1956

NON-FLAMMABLE GAS 2

RX ONLY

WARNING: Administration of this gas mixture 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 gas mixtures, 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. MIXTURES CONTAINING LESS THAN 19.5% OXYGEN MAY CAUSE RAPID SUFFOCATION.

Keep oil and grease away. Close valve after each use and when empty. Do not handle until all safety precautions have been read and understood. Open valve slowly. Protect from sunlight when ambient temperature exceeds 52 degrees C/125 degrees F. Store and use in a well ventilated place. Use a back flow preventive device in the piping. Use only with equipment cleaned for oxygen service and rated for cylinder pressure. FIRST AID: IF ACCIDENTLY INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician. DO NOT REMOVE THIS PRODUCT LABEL.

Medical-Technical Gases, Inc.

8 Executive Park Drive

North Billerica, MA

Tel 800 FINE GAS

Fax (781) 395-9098

www.medtechgases.com

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Since 1961

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(06/14)

HELIUM OXYGEN MIXTURE

helium oxygen mixture gas

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:10736-013 |
| Route of Administration | RESPIRATORY (INHALATION) | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| HELIUM (UNII: 206GF3GB41) (HELIUM - UNII:206GF3GB41) | HELIUM | 800 mL in 1 L |
| OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065) | OXYGEN | 200 mL in 1 L |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------|----------------------|--------------------|
| 1 | NDC:10736-013-01 | 620 L in 1 CYLINDER | | |
| 2 | NDC:10736-013-02 | 5703 L in 1 CYLINDER | | |
| 3 | NDC:10736-013-03 | 7744 L in 1 CYLINDER | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved medical gas | | 05/01/2014 | |

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|------------------------|
| Medtech Gases Inc | | 066397297 | manufacture(10736-013) |

Revised: 5/2014

Medical-technical Gases, Inc.