

HELIUM - helium gas
Encompass Medical & Specialty Gases, Ltd.

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 Label

HELIUM COMPRESSED, USP UN1046
NON-FLAMMABLE GAS 2 37580 (R 06/05)

Rx only. **WARNING:** Administration of Helium may be hazardous or contraindicated. For use only by or under 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. **CAUTION: HIGH PRESSURE GAS. CAN CAUSE RAPID SUFFOCATION.** Store and use with adequate ventilation. Use equipment rated for cylinder pressure. Use a back flow preventive device in the piping. Cylinder temperatures should not exceed 52C (125F). Close valve after each use and when empty. Use in accordance with the Material Safety Data Sheet (MSDS). Inhaling Helium to alter the voice may prove fatal and should not be permitted. **FIRST AID: IF INHALED,** remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician. CAS: 7440-59-7

DO NOT REMOVE THIS PRODUCT LABEL.

Cylinders must be refilled by:

Encompass Medical and Specialty Gases, LTD. 4646 Linden Road P.O. Box 5404 Rockford, IL 61109
CONTENTS: LTRS CU. FT.



HELIUM			
helium gas			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:48883-006

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:48883-006-01	91 L in 1 CYLINDER		
2	NDC:48883-006-02	144 L in 1 CYLINDER		
3	NDC:48883-006-03	377 L in 1 CYLINDER		
4	NDC:48883-006-04	624 L in 1 CYLINDER		
5	NDC:48883-006-05	3101 L in 1 CYLINDER		
6	NDC:48883-006-06	6201 L in 1 CYLINDER		
7	NDC:48883-006-07	8143 L in 1 CYLINDER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved medical gas		04/15/2009	

Labeler - Encompass Medical & Specialty Gases, Ltd. (963344143)

Establishment

Name	Address	ID/FEI	Business Operations
Encompass Medical & Specialty Gases, Ltd.		963344143	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Encompass Medical & Specialty Gases, Ltd.		963719286	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Encompass Medical & Specialty Gases, Ltd.		963719096	manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Encompass Medical & Specialty Gases, Ltd.		963718361	manufacture