

**HELIUM OXYGEN MIX - helium oxygen mix 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 Oxygen Mix Label**

COMPRESSED GAS , OXIDIZING, N.O.S. (70% HELIUM USP, 30% OXYGEN USP) UN 3156  
 NON-FLAMMABLE GAS 2 OXIDIZER 5.1  
 34313 (01/09) OXYGEN CONTENT OVER 23.5%

Rx only. CAUTION: Federal law prohibits dispensing without prescription. WARNING: Administration of this gas 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 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: HIGH PRESSURE OXIDIZING GAS. MAY VIGOROUSLY ACCELERATE COMBUSTION. Store and use with adequate ventilation. Keep oil and grease away. Use only with equipment cleaned for oxygen service and rated for cylinder pressure. Use a back flow preventive device in the piping. Cylinder temperatures should not exceed 52C (125F). Open valve slowly. Close valve after each use and when empty. Use in accordance with the Material Safety Data Sheet (MSDS). FIRST AID: IF INHALED, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician. HELIUM CAS: 7440-59-7 OXYGEN CAS: 7782-44-7  
 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.



<b>HELIUM OXYGEN MIX</b>			
helium oxygen mix gas			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:48883-007
<b>Route of Administration</b>	RESPIRATORY (INHALATION)		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Helium (UNII: 206GF3GB41) (Helium - UNII:206GF3GB41)	Helium	500 mL in 1 L
Oxygen (UNII: S88TT14065) (Oxygen - UNII:S88TT14065)	Oxygen	500 mL in 1 L

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48883-007-01	617 L in 1 CYLINDER		
2	NDC:48883-007-02	623 L in 1 CYLINDER		
3	NDC:48883-007-03	629 L in 1 CYLINDER		
4	NDC:48883-007-04	640 L in 1 CYLINDER		
5	NDC:48883-007-05	654 L in 1 CYLINDER		
6	NDC:48883-007-06	5689 L in 1 CYLINDER		
7	NDC:48883-007-07	5743 L in 1 CYLINDER		
8	NDC:48883-007-08	5796 L in 1 CYLINDER		
9	NDC:48883-007-09	5904 L in 1 CYLINDER		
10	NDC:48883-007-10	6009 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