

**OXYGEN- oxygen gas**  
**Founders Healthcare LLC, dba Preferred Homecare**

*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.*

**Oxygen**

**Principal for Oxygen Product**

**OXYGEN,  
COMPRESSED USP  
UN 1072**

**DANGER:**  
MAY CAUSE OR INTENSIFY FIRE; OXIDIZER.  
CONTAINS GAS UNDER PRESSURE;  
MAY EXPLODE IF HEATED.



Do not handle until all safety precautions have been read and understood. Keep and store away from clothing and other combustible materials. Keep valves and fittings free from grease and oil. Use and store only outdoors or in a well-ventilated place. In case of fire: Stop leak if safe to do so. Use a back flow preventive device in the piping. Use only with equipment of compatible materials of construction and rated for cylinder pressure. Use only with equipment cleaned for oxygen service. Open valve slowly. 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.

CAS NO: 7782-44-7

Contents	Size
113 Liters	<input type="checkbox"/> M4
165 Liters	<input type="checkbox"/> M6
255 Liters	<input type="checkbox"/> C
425 Liters	<input type="checkbox"/> D
680 Liters	<input type="checkbox"/> E
7080 Liters	<input type="checkbox"/> H
____ Liters	<input type="checkbox"/> Other

DO NOT REMOVE THIS PRODUCT LABEL.

WARNING: For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, **Rx only**. Uninterrupted use of high concentrations of oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful. Do not attempt to use on patients who have stopped breathing unless used in conjunction with resuscitative equipment. Produced by Air Liquefaction. ©Applied Home Healthcare Equipment 2014

**Representative Labeling  
pursuant to 21 CFR 207.3 (10)  
Company name and contact information  
are printed in this box**

OXYGEN

COMPRESSED

USP

UN 1072

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<b>OXYGEN</b>				
oxygen gas				
<b>Product Information</b>				
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:64346-001	
<b>Route of Administration</b>	RESPIRATORY (INHALATION)			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065)		OXYGEN	99 L in 100 L	
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64346-001-01	113 L in 1 CYLINDER; Type 0: Not a Combination Product	05/05/2011	
2	NDC:64346-001-02	164 L in 1 CYLINDER; Type 0: Not a Combination Product	05/05/2011	
3	NDC:64346-001-03	255 L in 1 CYLINDER; Type 0: Not a Combination Product	05/05/2011	
4	NDC:64346-001-04	425 L in 1 CYLINDER; Type 0: Not a Combination Product	05/05/2011	
5	NDC:64346-001-05	640 L in 1 CYLINDER; Type 0: Not a Combination Product	05/05/2011	
6	NDC:64346-001-06	680 L in 1 CYLINDER; Type 0: Not a Combination Product	05/05/2011	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
unapproved medical gas		05/01/2003		

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Founders Healthcare L.L.C., dba Preferred Homecare		003519734	manufacture(64346-001)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Founders Healthcare LLC, dba Preferred Homecare		144305583	manufacture(64346-001)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Founders Healthcare LLC, dba Preferred Homecare		187484816	manufacture(64346-001)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Founders Healthcare LLC, dba Preferred Homecare		189893451	manufacture(64346-001)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Founders Healthcare LLC, dba Preferred Homecare		832563097	manufacture(64346-001)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Founders Healthcare LLC, dba Preferred Homecare		869507236	manufacture(64346-001)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Founders Healthcare, L.L.C. dba Preferred Homecare		963617840	manufacture(64346-001)

Revised: 3/2019

Founders Healthcare LLC, dba Preferred Homecare