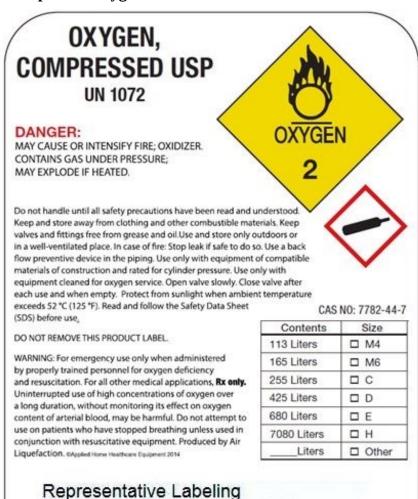
OXYGEN- oxygen gas Founders Healthcare LLC, dba Preferred Homecare

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



pursuant to 21 CFR 207.3 (10)

are printed in this box

Company name and contact information

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

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.

OXYGEN

oxygen gas

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64346-001
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065)	OXYGEN	99 L in 100 L

P	ackaging			
#	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	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved medical gas		05/01/2003			

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

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

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

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

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

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

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

Revised: 3/2019 Founders Healthcare LLC, dba Preferred Homecare