OXYGEN- oxygen gas First Community Care

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



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

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.



Representative Labeling pursuant to 21 CFR 207.3 (10)

OXYGEN oxygen gas Product Information Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:63121-123 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	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63121- 123-03	164 L in 1 CYLINDER; Type 0: Not a Combination Product	05/18/2010	
2	NDC:63121- 123-12	255 L in 1 CYLINDER; Type 0: Not a Combination Product	05/18/2010	
3	NDC:63121- 123-11	1738 L in 1 CYLINDER; Type 0: Not a Combination Product	05/18/2010	
4	NDC:63121- 123-08	7080 L in 1 CYLINDER; Type 0: Not a Combination Product	05/18/2010	
5	NDC:63121- 123-04	415 L in 1 CYLINDER; Type 0: Not a Combination Product	05/18/2010	
6	NDC:63121- 123-05	682 L in 1 CYLINDER; Type 0: Not a Combination Product	05/18/2010	
7	NDC:63121- 123-13	3455 L in 1 CYLINDER; Type 0: Not a Combination Product	05/18/2010	

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	08/01/1996		
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date	

Labeler - First Community Care (002729945)

Establishment				
Name	Address	ID/FEI	Business Operations	
First Community Care		002729945	manufacture(63121-123)	

Establishment				
Name	Address	ID/FEI	Business Operations	
First Community Care, LLC		023135986	manufacture(63121-123)	

Establishment			
Name	Address	ID/FEI	Business Operations
First Community Care, LLC		078480052	manufacture(63121-123)

Establishment				
Name	Address	ID/FEI	Business Operations	
Americoast Maine, LLC		189986263	manufacture(63121-123)	

Revised: 10/2023 First Community Care