OXYGEN- oxygen gas Florida Palliative Equipment L.L.C. dba Accent Medical

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, USP

Principal for Oxygen Product

EXPIRATION DATE

Representative Labeling pursuant to 21 CFR 207.3 (10)

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.

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. 6Applied Home Healthcare Equipment 2014

CAS N0: 7782-44-7 ontents Size

Contents	Size
113 Liters	□ M4
165 Liters	□ M6
255 Liters	□С
425 Liters	□ D
680 Liters	□ E
7080 Liters	□н
Liters	□ Other

Accent Medical

2891 SE 62nd Street, Ocala, FL 34480

352-622-7260

Federal Law Requires that this Container be Refilled with Oxygen U.S.P. Only by Establishments Registered as a Drug Producer in accordance with the Federal Food, Drug and Cosmetic Act. Warning — uninterrupted use of high concentrations of oxygen for more than five hours may be harmful. Do not attempt to use on patients who have stopped breathing, unless used in conjunction with resuscitative equipment. Keep Out of Reach of Children. Contents under high pressure and can vigorously accelerate combustion. Keep free from oil and grease. Do not use or store near heat or open flame and use only with equipment conditioned for oxygen service.

OXYGEN

COMPRESSED

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OXYGEN

oxygen gas

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61580-123	
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:61580-123- 02	255 L in 1 CYLINDER; Type 0: Not a Combination Product	01/19/2012	
2	NDC:61580-123- 03	425 L in 1 CYLINDER; Type 0: Not a Combination Product	01/19/2012	
3	NDC:61580-123- 01	164 L in 1 CYLINDER; Type 0: Not a Combination Product	01/19/2012	
4	NDC:61580-123- 04	680 L in 1 CYLINDER; Type 0: Not a Combination Product	01/19/2012	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved medical gas		01/19/2012		

Labeler - Florida Palliative Equipment L.L.C. dba Accent Medical (013070819)

Establishment					
Name	Address	ID/FEI	Business Operations		
Florida Palliative Equipment L.L.C. dba Accent Medical		013070819	manufacture(61580-123)		

Revised: 10/2023 Florida Palliative Equipment L.L.C. dba Accent Medical