OXYGEN- oxygen gas Pacific Island Medical, Inc.

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



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

OXYGEN

COMPRESSED

USP

UN 1072

PRODUCED BY AIR LIQUIFICATION

WARNING: HIGH PRESSURE OXIDIZING GAS, VIGOROUSLY ACCELERATES COMBUSTION. NO SMOKING IN THE PRESENCE OF OXYGEN OR A FIRE MAY RESULT.

WARNING: For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx only.

WARNING: Federal law prohibits dispensing without prescription. Uninterrupted use of high concentrations of oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful. Use only with pressure reducing equipment and apparatus designed for oxygen. Do not attempt to use on patients who have stopped breathing, unless used in conjuction with resuscitative equipment.

WARNING: Keep oil and grease away. Use only with equipment cleaned for oxygen service and rated for cylinder pressure. Open valve slowly. Close valve after each use and when empty.

USE IN ACCORDANCE WITH MATERIAL SAFETY DATA SHEET.

DO NOT REMOVE THIS PRODUCT LABEL.



Representative Labeling pursuant to 21 CFR 207.3 (10)

OXYGEN

oxygen gas

Droduct	Information	
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Route of Administration

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64395-0001

RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

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

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64395- 0001-1	165 L in 1 CYLINDER; Type 0: Not a Combination Product	12/23/2009	
2	NDC:64395- 0001-2	415 L in 1 CYLINDER; Type 0: Not a Combination Product	12/23/2009	
3	NDC:64395- 0001-3	682 L in 1 CYLINDER; Type 0: Not a Combination Product	12/23/2009	
4	NDC:64395- 0001-4	3532 L in 1 CYLINDER; Type 0: Not a Combination Product	12/23/2009	

Marketing Information			
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
	12/23/2009		
	Application Number or Monograph	Application Number or Monograph Marketing Start Citation Date	

Labeler - Pacific Island Medical, Inc. (867986994)

Establishment					
Name	Address	ID/FEI	Business Operations		
Pacific Island Medical, Inc.		867986994	manufacture(64395-0001)		

Revised: 10/2023 Pacific Island Medical, Inc.