OXYGEN- oxygen gas Elixair 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



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									
Product Information									
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:27561-001						
Route of Administration	RESPIRATORY (INHALATION)								
Active Ingredient/Active Moiety									
Ingredie	Basis of Strength	Strength							
OXYGEN (UNII: S88TT14065) (OXY	OXYGEN	99 L in 100 L							

Packaging							
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:27561-001- 01	164 L in 1 CYLINDER; Type 0: Not a Combination Product	01/12/2017				
2	NDC:27561-001- 02	255 L in 1 CYLINDER; Type 0: Not a Combination Product	01/12/2017				
3	NDC:27561-001- 03	425 L in 1 CYLINDER; Type 0: Not a Combination Product	01/12/2017				
4	NDC:27561-001- 04	680 L in 1 CYLINDER; Type 0: Not a Combination Product	01/12/2017				
Marketing Information							
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
un ga	approved medica s	I	01/12/2017				

Labeler - Elixair Medical Inc (839214822)

Establishment								
Name	Address	ID/FEI	Business Operations					
Elixair Medical Inc		839214822	manufacture(27561-001)					

Revised: 10/2024

Elixair Medical Inc