OXYGEN- oxygen gas Southeastern Regional Medical Center dba Southeastern Home Medical Equipment

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



OXYGEN COMPRESSED USP UN 1072 PRODUCED BY AIR LIQUIFICATION WARNING: HICH PRESSURE OXIDIZ

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 Informa	ition			
Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61279-001
Route of Administra	ation	RESPIRATORY (INHALATION)		
Active Ingredien	t/Active Moi	ety		
Ingredient Name			Basis of Strengtl	n Strength
OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065)		OXYGEN	99 L in 100 L	
Packaging				
Packaging # Item Code		Package Description	Marketing Start Date	Marketing End Date
# Item Code		Package Description DER; Type 0: Not a Combination Product	Marketing Start Date 01/10/2000	Marketing End Date

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
unapproved medical gas		01/10/2000					

Labeler - Southeastern Regional Medical Center dba Southeastern Home Medical Equipment (010899341)

Establishment					
Name	Address	ID/FEI	Business Operations		
Southeastern Regional Medical Center dba Southeastern Home Medical Equipment		010899341	manufacture (6 1279 - 00 1)		

Revised: 11/2020

Southeastern Regional Medical Center dba Southeastern Home Medical Equipment