#### OXYGEN- oxygen gas Bay State 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.

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Oxygen

#### Principal for Oxygen Product



REFRIGERATED GAS; MAY CAUSE CRYOGENIC BURNS OR INJURY. COMBUSTIBLES IN CONTACT WITH LIQUID OXYGEN MAY EXPLODE ON IGNITION OR IMPACT.

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. Wear cold insulating gloves, face shield, and eye protection. 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. DO NOT change or force fit connections. Avoid spills. Do not walk on or roll equipment over spills. Close valve after each use and when empty. Always keep container in upright position. Read and follow the Safety Data Sheet (SDS) before use.

### FIRST AID:

# IF ON SKIN: <u>Thaw frosted parts with lukewarm water. Do not rub affected</u> <u>area. Get immediate medical advice/attention</u>.

#### 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) Company name and contact information are printed in this area

OXYGEN,	
REFRIGERATED	
LIQUID USP	
UN 1073	
CONTENTS	LITERS
CAS NO: 7782-44-7	
DANGER:	
MAY CAUSE OR INTENSIFY	FIRE; OXIDIZER. CONTAINS
REFRIGERATED GAS; MAY C	AUSE CRYOGENIC BURNS OR
INJURY. COMBUSTIBLES IN	CONTACT WITH LIQUID OXYGEN MAY EXPLODE ON
IGNITION OR IMPACT.	
Do not handle until all safety	precautions have been read and understood.
Keep and store away from a	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. Wear cold insulating gloves, face shield, and eye protection. 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. DO NOT change or force fit connections. Avoid spills. Do not walk on or roll equipment over spills. Close valve after each use and when empty. Always keep container in upright position. Read and follow the Safety Data Sheet (SDS) before use. FIRST AID:

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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.

## 100809 5 LOT EXPIRATION DATE 1014

#### OXYGEN

oxygen gas

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	ltem Code (Source)	NDC:62481-4565
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety		
Ingredient Name	<b>Basis of Strength</b>	Strength
<b>OXYGEN</b> (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065)	OXYGEN	99 L in 100 L

#### Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62481- 4565-4	1699 L in 1 CYLINDER; Type 0: Not a Combination Product	01/04/2010	
2	NDC:62481- 4565-6	425 L in 1 CYLINDER; Type 0: Not a Combination Product	01/04/2010	
3	NDC:62481- 4565-7	680 L in 1 CYLINDER; Type 0: Not a Combination Product	01/04/2010	
4	NDC:62481- 4565-8	41 L in 1 DEWAR; Type 0: Not a Combination Product	01/04/2010	
5	NDC:62481- 4565-9	31 L in 1 DEWAR; Type 0: Not a Combination Product	01/04/2010	
6	NDC:62481- 4565-0	21 L in 1 DEWAR; Type 0: Not a Combination Product	01/04/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved medical gas		01/04/2010	

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Bay State Medical, Inc.		624602439	manufacture(62481-4565)	

Revised: 10/2023

Bay State Medical, Inc.