OXYGEN- oxygen gas At Home 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.

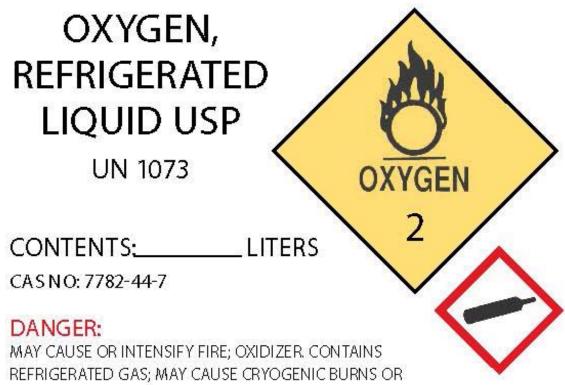
WARNING: For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx only.

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.



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 do thing 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 deaned 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	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: Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention.

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)

U)	XYGEN							
) X	ygen gas							
Ρ	roduct Infor	mation						
Product Type			HUMAN PRESCRIPTION DRUG	Item Code (Source)			NDC:60546-001	
Route of Administration		istration	RESPIRATORY (INHALATION)					
A	ctive Ingred	ient/Active	Moiety					
Ingredient Name			Basis of Strength			Strength		
o>	KYGEN (UNII: S88	3TT14065) (OXY	GEN - UNII:S88TT14065)	0>	YGEN		99 L in 100 L	
-								
	ackaging Item Code	Pa	ckage Description	M	arketing Start	M		
#			ckage Description NDER; Type 0: Not a Combination		arketing Start Date 9/2017	M	arketing End Date	
# 1	Item Code NDC:60546-	246 L in 1 CYLI Product		05/0	Date	M		
# 1 2	Item Code NDC:60546- 001-02 NDC:60546-	246 L in 1 CYLI Product 415 L in 1 CYLI Product	NDER; Type 0: Not a Combination	05/0 05/0	Date 9/2017	M		
# 1 2 3	Item Code NDC:60546- 001-02 NDC:60546- 001-03 NDC:60546-	246 L in 1 CYLI Product 415 L in 1 CYLI Product 682 L in 1 CYLI Product	NDER; Type 0: Not a Combination	05/0 05/0 05/0	Date 9/2017 9/2017	M		
# 1 2 3 4	Item Code NDC:60546- 001-02 NDC:60546- 001-03 NDC:60546- 001-04 NDC:60546- 001-04	246 L in 1 CYLI Product 415 L in 1 CYLI Product 682 L in 1 CYLI Product 170 L in 1 CYLI Product	NDER; Type 0: Not a Combination NDER; Type 0: Not a Combination NDER; Type 0: Not a Combination	05/0 05/0 05/0	Date 9/2017 9/2017 9/2017	M		
# 1 2	Item Code NDC:60546- 001-02 NDC:60546- 001-03 NDC:60546- 001-04 NDC:60546- 001-01 NDC:60546- 001-01	246 L in 1 CYLI Product 415 L in 1 CYLI Product 682 L in 1 CYLI Product 170 L in 1 CYLI Product 1700 L in 1 CYLI Product	NDER; Type 0: Not a Combination NDER; Type 0: Not a Combination NDER; Type 0: Not a Combination NDER; Type 0: Not a Combination	05/0 05/0 05/0 05/0	Date 9/2017 9/2017 9/2017 9/2017			
# 1 2 3 4 5 6	Item Code NDC:60546- 001-02 NDC:60546- 001-03 NDC:60546- 001-04 NDC:60546- 001-01 NDC:60546- 001-05 NDC:60546- 001-05	246 L in 1 CYLI Product 415 L in 1 CYLI Product 682 L in 1 CYLI Product 170 L in 1 CYLI Product 1700 L in 1 CYLI Product 3200 L in 1 CYLI Product	NDER; Type 0: Not a Combination NDER; Type 0: Not a Combination NDER; Type 0: Not a Combination NDER; Type 0: Not a Combination LINDER; Type 0: Not a Combination	05/0 05/0 05/0 05/0 05/0	Date 9/2017 9/2017 9/2017 9/2017 9/2017 9/2017		arketing End Date	

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
unapproved medical gas		05/09/2017			

Labeler - At Home Medical, Inc. (150622843)

Establishment						
Name	Address	11	D/FEI	Business Operations		
At Home Medical		1506228	43	manufacture(6	0546-001)	
Establishment						
Nam	e		Address	ID/FEI	Business Operations	
AHS Investment Corp. dba At Home Medical, Inc.				825199206	manufacture(60546-001)	

Establishment					
Name	Address	ID/FEI	Business Operations		
AHS Investment Corp. dba At Home Medical, Inc.		825199131	manufacture(60546-001)		

Revised: 10/2023

At Home Medical, Inc.