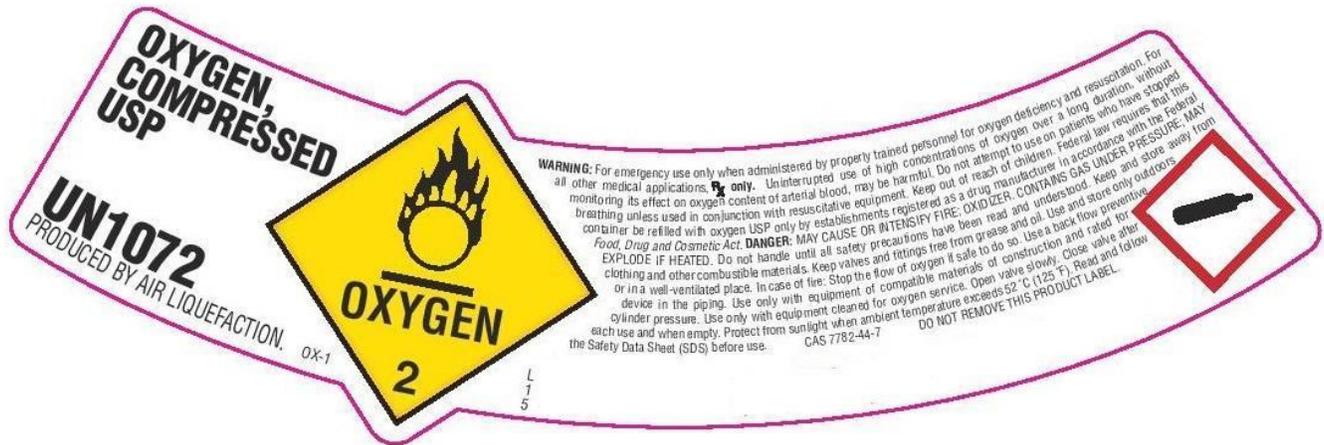
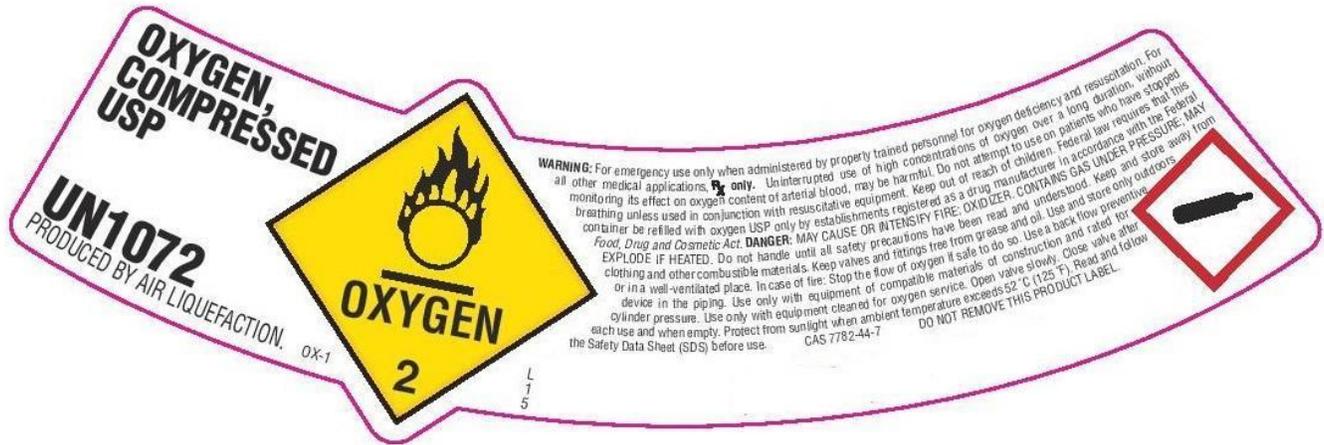


OXYGEN- oxygen gas
Rotech Healthcare Inc

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.

2018 DRUG REGISTRATION LISTING

Oxygen Compressed



Oxygen Refrigerated Liquid

**OXYGEN,
REFRIGERATED
LIQUID
USP**

UN1073

PRODUCED BY AIR LIQUEFACTION



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. Keep out of reach of children. Federal law requires that this container be refilled with oxygen USP only by establishments registered as a drug manufacturer in accordance with the Federal Food, Drug, and Cosmetic Act.

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 combustibles 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 the flow of oxygen 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. CAS: 7782-44-7

DO NOT REMOVE THIS PRODUCT LABEL.

**OXYGEN,
REFRIGERATED
LIQUID
USP**

UN1073

PRODUCED BY AIR LIQUEFACTION



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FIRST AID: IF ON SKIN: Thaw frosted parts with lukewarm water. Do not rub affected area. Get immediate medical advice/attention. CAS: 7782-44-7

DO NOT REMOVE THIS PRODUCT LABEL.

OXYGEN			
oxygen gas			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:57439-000
Route of Administration	RESPIRATORY (INHALATION)		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	OXYGEN (UNII: S88TT14065) (OXYGEN - UNII:S88TT14065)	OXYGEN	99 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57439-000-01	170 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
2	NDC:57439-000-02	255 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
3	NDC:57439-000-03	425 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
4	NDC:57439-000-04	680 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
5	NDC:57439-000-05	1738 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
6	NDC:57439-000-06	2549 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	
7	NDC:57439-000-07	3455 L in 1 CYLINDER; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved medical gas		01/01/2018	

OXYGEN

oxygen gas

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:57439-001
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57439-001-01	16750 L in 1 DEWAR; Type 0: Not a Combination Product	01/01/2018	
2	NDC:57439-001-02	24950 L in 1 DEWAR; Type 0: Not a Combination Product	01/01/2018	
3	NDC:57439-001-03	33500 L in 1 DEWAR; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved medical gas		01/01/2018	

Labeler - Rotech Healthcare Inc (144556222)

Establishment

Name	Address	ID/FEI	Business Operations
HOME CARE MEDICAL SERVICES		169932436	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ACTIVE CARE		174392501	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
SENTRY HOME HEALTH		796502123	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
THE OXYGEN STORE		949995476	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ALLIED MEDICAL SUPPLY		079488272	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH		159346050	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
SUMMIT RESPIRATORY		135922784	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
SUMMIT RESPIRATORY		874476422	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
OXYGEN PLUS		796499858	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ROTH MEDICAL		179387050	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
SUMMIT RESPIRATORY		831552372	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ROTH MEDICAL		144369613	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
G & G MEDICAL		796502479	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
G & G MEDICAL		085400138	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
DON PAUL RESPIRATORY SERVICES		796500895	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ROTH MEDICAL		831552364	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
SUMMIT RESPIRATORY		079569918	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ROTH MEDICAL		948744180	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH		831562918	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
KELLEY'S HOME HEALTH SERVICES		079738768	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
FAMILY HOME CARE		831748491	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
MEDSOURCE		079713679	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
HOOK'S OXYGEN & MEDICAL EQUIPMENT		079607405	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH		098136096	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
FIRST CARE		079639101	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
GREAT LAKES HOME MEDICAL		831831172	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
MIDLAND OXYGEN & MEDICAL SUPPLY		016953296	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
HEARTLAND HOME HEALTH CARE		079570162	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
HOME CARE MEDICAL		079721579	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH		611480690	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH		833186922	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
MAJOR MEDICAL		079607401	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
MAJOR MEDICAL		079607390	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
VITALCARE HEALTH SERVICES		956721187	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
CAMBRIA MEDICAL SUPPLY		620007021	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
CPO2		148713329	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
NORTHEAST MEDICAL EQUIPMENT INC		079531825	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH		058159881	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
HOME MEDICAL SYSTEMS		795469142	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH		079738728	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
MAJOR MEDICAL SUPPLY		079721904	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
MED-AIR TRANSFILL		841973667	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
RHEMA MEDICAL		078670599	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH		079570216	manufacture(57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
ROTECH HOME MEDICAL CARE		079607622	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
COMMUNITY HOME OXYGEN		079607617	manufacture(57439-000, 57439-001)

Establishment

Name	Address	ID/FEI	Business Operations
COMMUNITY HOME OXYGEN		796499213	manufacture(57439-001)

Revised: 1/2018

Rotech Healthcare Inc