

OXYGEN- oxygen gas

Complete Care 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

Principal for Oxygen Product

**OXYGEN,
COMPRESSED USP
UN 1072**



DANGER:
MAY CAUSE OR INTENSIFY FIRE; OXIDIZER.
CONTAINS GAS UNDER PRESSURE;
MAY EXPLODE IF HEATED.

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. 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. Open valve slowly. Close valve after each use and when empty. Protect from sunlight when ambient temperature exceeds 52 °C (125 °F). Read and follow the Safety Data Sheet (SDS) before use.

CAS NO: 7782-44-7

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. ©Applied Home Healthcare Equipment 2014

| Contents | Size |
|-------------|--------------------------------|
| 113 Liters | <input type="checkbox"/> M4 |
| 165 Liters | <input type="checkbox"/> M6 |
| 255 Liters | <input type="checkbox"/> C |
| 425 Liters | <input type="checkbox"/> D |
| 680 Liters | <input type="checkbox"/> E |
| 7080 Liters | <input type="checkbox"/> H |
| ____ Liters | <input type="checkbox"/> Other |

**Representative Labeling
pursuant to 21 CFR 207.3 (10)
Company name and contact information
are printed in this box**

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 conjunction 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.

LOT
EXPIRATION DATE

Representative Labeling
pursuant to 21 CFR 207.3 (10)

OXYGEN

oxygen gas

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|----------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:61398-0828 |
| 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:61398-0828-5 | 170 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/02/2009 | |
| 2 | NDC:61398-0828-6 | 255 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/02/2009 | |
| 3 | NDC:61398-0828-7 | 425 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/02/2009 | |
| 4 | NDC:61398-0828-8 | 680 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/02/2009 | |
| 5 | NDC:61398-0828-9 | 1738 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/02/2009 | |
| 6 | NDC:61398-0828-0 | 3455 L in 1 CYLINDER; Type 0: Not a Combination Product | 12/02/2009 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved medical gas | | 12/02/2009 | |

Labeler - Complete Care Inc (173531021)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|-------------------------|
| Complete Care Inc | | 178368804 | manufacture(61398-0828) |

Revised: 10/2023

Complete Care Inc