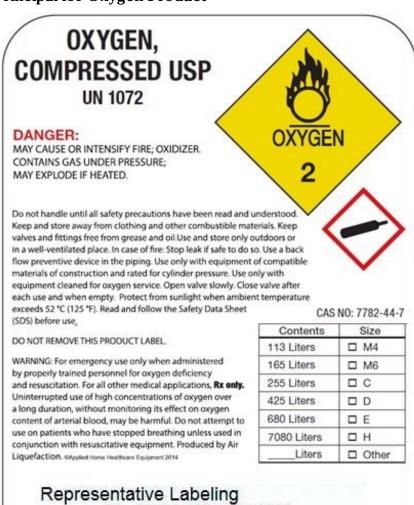
OXYGEN- oxygen gas Breathe E-Z Medical Equipment

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



pursuant to 21 CFR 207.3 (10)

are printed in this box

Company name and contact information

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.

OXYGEN

oxygen gas

| Product Information | | | |
|-------------------------|--------------------------|--------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:63428-001 |
| 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 | |

| P | Packaging | | | | |
|---|------------------|---|-----------------------------|---------------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:63428-001-01 | $682\ L$ in 1 CYLINDER; Type 0: Not a Combination Product | 05/22/2007 | | |
| 2 | NDC:63428-001-02 | 415 L in 1 CYLINDER; Type 0: Not a Combination Product | 05/22/2007 | | |
| 3 | NDC:63428-001-03 | 248 L in 1 CYLINDER; Type 0: Not a Combination Product | 05/22/2007 | | |
| 4 | NDC:63428-001-04 | 165 L in 1 CYLINDER; Type 0: Not a Combination Product | 05/22/2007 | | |

| Marketing Information | | | | |
|------------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| unapproved medical gas | | 05/22/2007 | | |
| | | | | |

Labeler - Breathe E-Z Medical Equipment (799982900)

Registrant - Breathe E-Z Medical Equipment (799982900)

| Establishment | | | | |
|-------------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Breathe E-Z Medical Equipment | | 799982900 | manufacture(63428-001) | |

Revised: 12/2018 Breathe E-Z Medical Equipment