

**OXYGEN- oxygen gas**  
**Bernens Convalescent Pharmacy, 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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**PRODUCT WARNINGS AND PRECAUTIONS**

FIRST AID: FOR OXYGEN DEFICIENCY IN BREATHING PERSONS OR EMERGENCY RESUSCITATION WHEN USED BY PERSONNEL INSTRUCTED IN OXYGEN ADMINISTRATION. FOR OTHER MEDICAL APPLICATIONS USE ONLY AS DIRECTED BY A LICENSED PRACTITIONER. 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 REMOVE THIS PRODUCT LABEL. CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION.

IN CASE OF FROSTBITE OBTAIN PROFESSIONAL MEDICAL TREATMENT IMMEDIATELY.

**OXYGEN REFRIGERATED LABEL**

OXYGEN U.S.P. REFRIGERATED LIQUID - OXYGEN UN 1073 PRODUCED BY AIR LIQUEFACTION

MARKETED BY BERNENS MEDICAL

WARNING: ALWAYS KEEP CONTAINER IN UPRIGHT POSITION. EXTREMELY COLD OXIDIZING LIQUID AND GAS UNDER PRESSURE. VIGOROUSLY ACCELERATES COMBUSTION. COMBUSTIBLES IN CONTACT WITH LIQUID OXYGEN MAY EXPLODE ON IGNITION OR IMPACT. CAN CAUSE SEVERE FROSTBITE. KEEP OIL, GREASE AND COMBUSTIBLES AWAY. USE ONLY WITH EQUIPMENT CLEANED FOR OXYGEN SERVICE. STORE AND USE WITH ADEQUATE VENTILATION. DO NOT GET LIQUID IN EYES, ON SKIN, OR CLOTHING. FOR LIQUID WITHDRAWAL WEAR FACE SHIELD AND GLOVES. DO NOT DROP OR HANDLE CONTAINER ROUGHLY. USE HAND TRUCK FOR CONTAINER MOVEMENT. AVOID SPILLS. DO NOT WALK ON OR ROLL EQUIPMENT OVER SPILLS. CLOSE VALVE AFTER EACH USE AND WHEN EMPTY. USE IN ACCORDANCE WITH COMPRESSED GAS ASSOCIATION PAMPHLETS G-4, G-4.1, G-4.4, P-1, P-12, AND P-14 AND WITH MATERIAL SAFETY DATA SHEET.

**WARNING:**

ALWAYS KEEP CONTAINER IN UPRIGHT POSITION.  
EXTREMELY COLD, OXIDIZING LIQUID AND GAS UNDER PRESSURE.  
VIGOROUSLY ACCELERATES COMBUSTION.  
COMBUSTIBLES IN CONTACT WITH LIQUID OXYGEN MAY  
EXPLODE ON IGNITION OR IMPACT.  
CAN CAUSE SEVERE FROSTBITE.

Keep oil, grease and combustibles away.  
Use only with equipment cleaned for oxygen service.  
Store and use with adequate ventilation.  
Do not get liquid in eyes, on skin, or clothing.  
For liquid withdrawal, wear face shield and gloves.  
Do not drop or handle container roughly.  
Use hand-truck for container movement.

Avoid spills. Do not walk on or roll equipment over spills.  
Close valve after each use and when empty.  
Use in accordance with Compressed Gas Association Pamphlets G-4,  
G-4.1, G-4.4, P-1, P-2, P-4, P-12 and P-14, and with material safety data  
sheet.

**IN CASE OF FROSTBITE,** obtain professional medical treatment  
immediately.

**First Aid:**

For oxygen deficiency in breathing persons or emergency resuscitation  
when used by personnel instructed in oxygen administration. For other  
medical applications, use only as directed by a licensed practitioner.  
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 REMOVE THIS PRODUCT LABEL.**

**CAUTION:** Federal Law prohibits dispensing without a prescription.

**OXYGEN**

oxygen gas

**Product Information**

|                                |                          |                           |                |
|--------------------------------|--------------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG  | <b>Item Code (Source)</b> | NDC:57957-0007 |
| <b>Route of Administration</b> | RESPIRATORY (INHALATION) |                           |                |

**Active Ingredient/Active Moiety**

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

**Packaging**

| # | Item Code        | Package Description                                      | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:57957-0007-1 | 25 L in 1 CYLINDER; Type 0: Not a Combination Product    | 01/01/1976           |                    |
| 2 | NDC:57957-0007-2 | 37 L in 1 CYLINDER; Type 0: Not a Combination Product    | 01/01/1976           |                    |
| 3 | NDC:57957-0007-3 | 400 L in 1 CYLINDER; Type 0: Not a Combination Product   | 01/01/1976           |                    |
| 4 | NDC:57957-0007-4 | 630 L in 1 CYLINDER; Type 0: Not a Combination Product   | 01/01/1976           |                    |
| 5 | NDC:57957-0007-5 | 6900 L in 1 CYLINDER; Type 0: Not a Combination Product  | 01/01/1976           |                    |
| 6 | NDC:57957-0007-6 | 22800 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1976           |                    |
| 7 | NDC:57957-0007-7 | 28800 L in 1 CYLINDER; Type 0: Not a Combination Product | 01/01/1976           |                    |

## Marketing Information

| Marketing Category     | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|------------------------|--|----------------------|--------------------|
| unapproved medical gas |  | 01/01/1976           |                    |

**Labeler** - Bernens Convalescent Pharmacy, Inc (041603101)

**Registrant** - Bernens Convalescent Pharmacy, Inc (041603101)

## Establishment

| Name                               | Address | ID/FEI    | Business Operations     |
|------------------------------------|---------|-----------|-------------------------|
| Bernens Convalescent Pharmacy, Inc |         | 041603101 | manufacture(57957-0007) |

Revised: 12/2025

Bernens Convalescent Pharmacy, Inc