

OXYGEN- oxygen gas

P.A.L. Home Diagnostics & Respiratory 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

C.A.S No. 7782-44-7

WARNING: HIGH PRESSURE, OXIDIZING GAS, VIGOROUSLY ACCELERATES COMBUSTION.

Keep oil and grease away. Open valve slowly. Store and use with adequate ventilation.

Use only with equipment cleaned for oxygen service and rated for cylinder pressure.

Use a back flow preventative device in the piping.

Close valve after each use and when empty. Cylinder temperatures should not exceed 52°C (125°F).

Use in accordance with Material Safety Data Sheet (MSDS).

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. 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.

Produced by Air Liquefaction

OXYGEN, COMPRESSED USP

UN 1072



C.A.S. NO. 7782-44-7

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

⚠ WARNING: HIGH PRESSURE, OXIDIZING GAS, VIGOROUSLY ACCELERATES COMBUSTION.

NO SMOKING IN THE PRESENCE OF OXYGEN OR A FIRE MAY RESULT.

Keep oil and grease away. Open valve slowly. Store and use with adequate ventilation.

Use only with equipment cleaned for oxygen service and rated for cylinder pressure.

Use a back flow preventative device in the piping.

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Size	Contents	Size	Contents
<input type="checkbox"/> "M6"	170 Liters	<input type="checkbox"/> "E"	682 Liters
<input type="checkbox"/> "C"	248 Liters	<input type="checkbox"/> "H"	6910 Liters
<input type="checkbox"/> "D"	415 Liters	<input type="checkbox"/> Other	____ Liters

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:68046-001
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:68046-001-01	164 L in 1 CYLINDER		
2	NDC:68046-001-02	225 L in 1 CYLINDER		
3	NDC:68046-001-03	425 L in 1 CYLINDER		
4	NDC:68046-001-04	680 L in 1 CYLINDER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved medical gas		08/23/2013	

Labeler - P.A.L. Home Diagnostics & Respiratory Care Inc. (066792636)

Registrant - P.A.L. Home Diagnostics & Respiratory Care Inc (066792636)

Establishment

Name	Address	ID/FEI	Business Operations
P.A.L. Home Diagnostics & Respiratory Care Inc		066792636	manufacture(68046-001)

Revised: 8/2013

P.A.L. Home Diagnostics & Respiratory Care Inc.