OXYGEN- oxygen gas MidMichigan Visiting Nurse Association dba MidMichigan Home Care

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, USP

Principal for Oxygen Product



OXYGEN COMPRESSED USP UN 1072 PRODUCED BY AIR LIQUIFICATION WARNING: HICH PRESSURE OXIDIZ

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 conjuction 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.



Representative Labeling pursuant to 21 CFR 207.3 (10)

| _ | | | | | | | | | |
|---|--------------------|------------------|---|----------------------|--------------------|--|--|--|--|
| 0 | XYGEN | | | | | | | | |
| ox | ygen gas | | | | | | | | |
| | | | | | | | | | |
| P | roduct Informa | tion | | | | | | | |
| P | roduct T ype | | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:59954-001 | | | | |
| R | oute of Administra | tion | RESPIRATORY (INHALATION) | | | | | | |
| | | | | | | | | | |
| | | | | | | | | | |
| Active Ingredient/Active Moiety | | | | | | | | | |
| Ingredient Na | | | ient 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:59954-001-02 | 425 L in 1 CYLIN | IDER; Type 0: Not a Combination Product | 09/01/2018 | | | | | |
| 2 | NDC:59954-001-03 | 680 L in 1 CYLI | NDER; Type 0: Not a Combination Product | 09/01/2018 | | | | | |

| Marketing Information | | | | | | | | | |
|------------------------|--|----------------------|--------------------|--|--|--|--|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | | | | | |
| unapproved medical gas | | 09/01/2018 | | | | | | | |
| | | | | | | | | | |

Labeler - MidMichigan Visiting Nurse Association dba MidMichigan Home Care (106873698)

Registrant - MidMichigan Visiting Nurse Association dba MidMichigan Home Care (937747678)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|----------------------------|
| | | | Duomeoo operationo |
| MidMichigan Visiting Nurse Association dba MidMichigan Home Care | | 937747678 | manufacture(59954-001) |

Revised: 10/2019

MidMichigan Visiting Nurse Association dba MidMichigan Home Care