

ULSPIRA- nitric oxide gas
Airgas Therapeutics, LLC

Nitric Oxide 800 PPM

WARNING: Administration of this gas mixture may be hazardous or contraindicated. For use only by or under the supervision of a licensed practitioner who is experienced in the use and administration of gas mixtures, and if familiar with the indications, effects, dosages, methods, and frequency and duration of administration, and with the hazards, contraindications and side effects and the precautions to be taken.

Ulspira TM

(nitric oxide for inhalation)

800 PPM

Rx Only

CAUTION: HIGH PRESSURE GAS. CAN CAUSE RAPID SUFFOCATION WITHOUT WARNING. Use equipment rated for cylinder pressure. Store and use with adequate ventilation. Secure cylinder in use and storage. Close valve after each use and when empty. USE IN ACCORDANCE WITH APPROPRIATE SDS.

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FIRST AID: IF INHALED, remove person to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical help.

RETURN WITH 25 PSIG.

TO BE REFILLED ONLY BY A PHARMACEUTICAL FACILITY

AUTHORIZED BY AIRGAS THERAPEUTICS, LLC

Manufactured Under Pharmaceutical Current Good Manufacturing Practices (cGMPs).

DO NOT REMOVE THIS PRODUCT LABELS

Store at 25 C (77 F) with excursions permitted between 15 - 30 C (59 - 86 F).

Volume 362 Liters

Airgas Therapeutics

An Air Liquide company

Manufactured by:

AIRGAS THERAPEUTICS, LLC

6141

Easton Road

Plumsteadville, PA 18949-0310

For Product Inquiry 1-833-ULSPIRA (857-7472)

UN 1956

COMPRESSED GAS, N.O.S. (NITRIC OXIDE, NITROGEN) 2.2

Net Weight: 0.4 kg

LOT:

EXP:

NDC 82605-005-02

Label No. ULSMD15 Rev. 00

800PPM MD15

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(nitric oxide for inhalation)
800 PPM

Rx Only

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Plumsteadville, PA 18949-0310
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(857-7472)

LOT:
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(NITRIC OXIDE, NITROGEN)
2.2
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Volume 2138 Liters

Airgas Therapeutics

An Air Liquide company

Manufactured by:

AIRGAS THERAPEUTICS, LLC

6141 Easton Road

Plumsteadville, PA 18949-0310

For Product Inquiry 1-833-ULSPIRA (857-7472)

UN1956

COMPRESSED GAS, N.O.S. (NITRIC OXIDE, NITROGEN) 2.2

Net Weight: 2.5 kg

LOT:

EXP:

NDC 82605-005-01

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(nitric oxide for inhalation)

800 PPM

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Manufactured Under Pharmaceutical Current Good

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Volume 2138 Liters

Airgas Therapeutics

an Air Liquide company

Manufactured by:

AIRGAS THERAPEUTICS, LLC
6141 Easton Road
Plumsteadville, PA 18949-0310
For Product Inquiry 1-833-ULSPIRA
(857-7472)

UN 1956
COMPRESSED GAS, N.O.S.
(NITRIC OXIDE, NITROGEN)

2.2

Net Weight: 2.5 kg

LOT:
EXP:
NDC 82605-005-01



800PPM NO88

Label No. ULSNO88 Rev. 00

ULSPIRA

nitric oxide gas

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:82605-008
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITRIC OXIDE (UNII: 31C4KY9ESH) (NITRIC OXIDE - UNII:31C4KY9ESH)	NITRIC OXIDE	0.8 mL in 100 L

Inactive Ingredients

Ingredient Name	Strength
NITROGEN (UNII: N762921K75)	999.2 mL in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:82605-008-01	2138 L in 1 CYLINDER; Type 0: Not a Combination Product	08/04/2023	
2	NDC:82605-008-02	362 L in 1 CYLINDER; Type 0: Not a Combination Product	08/04/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203144	08/04/2023	

Labeler - Airgas Therapeutics, LLC (118537769)

Establishment

Name	Address	ID/FEI	Business Operations
Airgas Therapeutics, LLC		118537769	manufacture(82605-008)

Revised: 10/2024

Airgas Therapeutics, LLC