

XENON- xenon xe-133 gas
Lantheus Medical Imaging, Inc.

XENON Xe 133 GAS

FOR DIAGNOSTIC USE

DESCRIPTION:

Xenon Xe 133 Gas is supplied in a mixture of xenon gas (5%) in carbon dioxide (95%). It is contained within septum sealed glass vials and is suitable for inhalation in the diagnostic evaluation of pulmonary function and imaging, as well as assessment of cerebral blood flow. Xenon Xe 133 Gas is reactor-produced as a by-product of Uranium U235 fission. Each vial contains the labeled amount of Xenon Xe 133 radioactivity at the time of calibration. The contents of the vial are in gaseous form, contain no preservatives, and are ready for use.

Xenon Xe 133 is chemically and physiologically related to elemental Xenon, a non-radioactive monoatomic gas which is physiologically inert except for anesthetic properties at high doses.

PHYSICAL CHARACTERISTICS

Xenon Xe 133 decays by beta and gamma emissions with a half-life of 5.245 days.¹ Significant radiations which are emitted by the nuclide are listed in Table 1.

Table 1. Principal Radiation Emission Data from Xenon-133

Radiation	Mean Energy (KeV)	Mean % per Disintegration
Beta-2	100.6	99.3
Ce-K-2	45.0	53.3
Ce-L-2	75.3	8.1
Ce-M-2	79.8	1.7
Gamma-2	81.0	36.5
K _{α2} X-ray	30.6	13.6
K _{α1} X-ray	31.0	25.3
K _β X-ray	35.0	9.1

¹ Kocher, David C., "Radioactive Decay Data Tables," DOE/TIC-11026, p. 138,1981.

EXTERNAL RADIATION

The specific gamma ray constant for Xenon Xe 133 is 3.6 microcoulombs/Kg-MBq-hr (0.51R/hr-mCi) at 1 cm. The first half value thickness of lead is 0.0035 cm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from the interposition of various thicknesses of Pb is shown in Table 2. For example, the use of 0.20 cm of Pb will decrease the external radiation exposure by a factor of 1,000.

Table 2. Radiation Attenuation by Lead Shielding

cm of Pb	Radiation Attenuation Factor
0.0035	0.5

0.037	10^{-1}
0.12	10^{-2}
0.20	10^{-3}
0.29	10^{-4}

To correct for physical decay of this radionuclide, the fractions that remain at selected time intervals after the time of calibration are shown in Table 3.

Table 3. Xenon Xe 133 Physical Decay Chart (Half Life 5.245 days)

Day	Fraction Remaining	Day	Fraction Remaining
0*	1.000	8	.349
1	.877	9	.302
2	.768	10	.268
3	.674	11	.235
4	.591	12	.206
5	.518	13	.181
6	.452	14	.157
7	.398		

* Calibration Day

CLINICAL PHARMACOLOGY:

Xenon Xe 133 is a readily diffusible gas which is neither utilized nor produced by the body. It passes through cell membranes and freely exchanges between blood and tissue. It tends to concentrate more in body fat than in blood, plasma, water or protein solutions. In the concentrations used for diagnostic purposes it is physiologically inactive. Inhaled Xenon Xe 133 Gas will enter the alveolar wall and enter the pulmonary venous circulation via the capillaries. Most of the Xenon Xe 133 that enters the circulation from a single breath is returned to the lungs and exhaled after a single pass through the peripheral circulation.

INDICATIONS AND USAGE:

Inhalation of Xenon Xe 133 Gas has proved valuable for the evaluation of pulmonary function and for imaging the lungs. It may also be applied to assessment of cerebral flow.

CONTRAINDICATIONS:

None known.

WARNINGS:

Xenon Xe 133 Gas delivery systems, i.e., respirators or spirometers, and associated tubing assemblies must be leakproof to avoid loss of radioactivity into the environs not specifically protected by exhaust systems.

Xenon Xe 133 adheres to some plastics and rubber and should not be allowed to stand in tubing or respirator containers. The unrecognized loss of radioactivity from the dose for administration may

render the study non-diagnostic.

The vial stopper contains dry natural rubber latex and may cause allergic reactions in providers or patients who are sensitive to latex.

PRECAUTIONS:

General

Xenon Xe 133, as well as other radioactive drugs, must be handled with care and appropriate safety measures should be used to minimize radiation exposure to clinical personnel. Also, care should be taken to minimize radiation exposure to patients consistent with proper patient management.

Exhaled Xenon Xe 133 Gas should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of radionuclides.

Radiopharmaceuticals should be used only by physicians who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long term animal studies have been performed to evaluate carcinogenic potential or whether Xenon Xe 133 affects fertility in males or females.

Pregnancy

Animal reproductive studies have not been conducted with Xenon Xe 133 Gas. It is also not known whether Xenon Xe 133 Gas can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Xenon Xe 133 Gas should be given to a pregnant woman only if clearly needed.

Ideally, examination using radiopharmaceuticals, especially those elective in nature in a woman of childbearing capability, should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

It is not known whether Xenon Xe 133 is excreted in human milk. Many drugs are excreted in human milk, therefore formula feedings should be substituted for breast feeding, because of the potential for adverse reactions in nursing infants.

Pediatric Use

Safety and effectiveness in the pediatric population has not been established.

Geriatric Use

Clinical studies of Xenon Xe 133 Gas did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosage range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS:

Adverse reactions related to the use of this agent have not been reported to date.

DOSAGE AND ADMINISTRATION:

Xenon Xe 133 Gas is administered by inhalation from closed respirator systems or spirometers.

The suggested activity range employed for inhalation by the average adult patient (70 kg) is:

Pulmonary function including imaging: 74-1110MBq (2-30mCi) in 3 liters of air.

Cerebral blood flow: 370-1110MBq (10-30mCi) in 3 liters of air.

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration.

RADIATION DOSIMETRY

The estimated absorbed radiation doses² to an average patient (70 kg) for pulmonary perfusion and cerebral blood flow studies from a maximum dose of 1110 MBq (30mCi) of Xenon Xe 133 in 3 liters of air are shown in Table 4.

Table 4. Radiation Doses

	Effective Half-Time	Lungs*	Brain mGy/1110MBq	Whole Body (rads/30mCi)
Pulmonary Perfusion	2 min.	2.5(0.25)	0.014(0.0014)	0.027(0.0027)
Cerebral Blood Flow	5 min.	6.3(0.63)	0.035(0.0035)	0.068(0.0068)

* 99% of activity is in lungs.

² Method of Calculation: A Schema for Absorbed-Dose Calculation for Biologically Distributed Radionuclides, Supplement No. 1, MIRD pamphlet No. 1, J. Nucl. Med., p.7 (1968).

HOW SUPPLIED:

The Xenon Xe 133 Gas is supplied as part of the Calidose™ system, consisting of 3ml unit dose vials and the Calidose™ dispenser for shielded dispensing.

Normally vials containing either 370 or 740MBq (10 or 20mCi)/vial, packed 1 vial or 5 vials per shield tube, are supplied.

The NDC number for: 10mCi vial is 11994-127; 20mCi vial is 11994-128.

Store at room temperature.

This radiopharmaceutical is approved for distribution to persons licensed pursuant to the Code of Massachusetts Regulations 105 CMR 120.100 for the uses listed in 105 CMR 120.547 or 120.552 or under equivalent regulations of the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State.

The contents of the vial are radioactive. Adequate shielding and handling precautions must be maintained.

Lantheus Medical Imaging, Inc.

331 Treble Cove Rd., N. Billerica, MA 01862 USA

For Ordering Tel. Toll Free 800-299-3431

(For Massachusetts & International, Call 978-667-9531)

All Other Business 800-362-2668

Patent: <http://www.lantheus.com/patents/index.html>

Printed in U.S.A.

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PRINCIPAL DISPLAY PANEL - 10mCi Vial Label

515129-0811

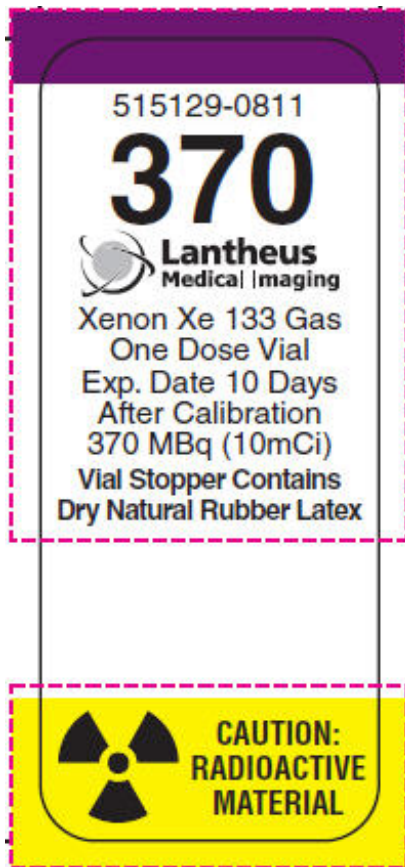
370

Lantheus
Medical Imaging

Xenon Xe 133 Gas
One Dose Vial
Exp. Date 10 Days
After Calibration
370 MBq (10mCi)

Vial Stopper Contains
Dry Natural Rubber Latex

CAUTION:
RADIOACTIVE
MATERIAL



PRINCIPAL DISPLAY PANEL - 20mCi Vial Label

515130-0811

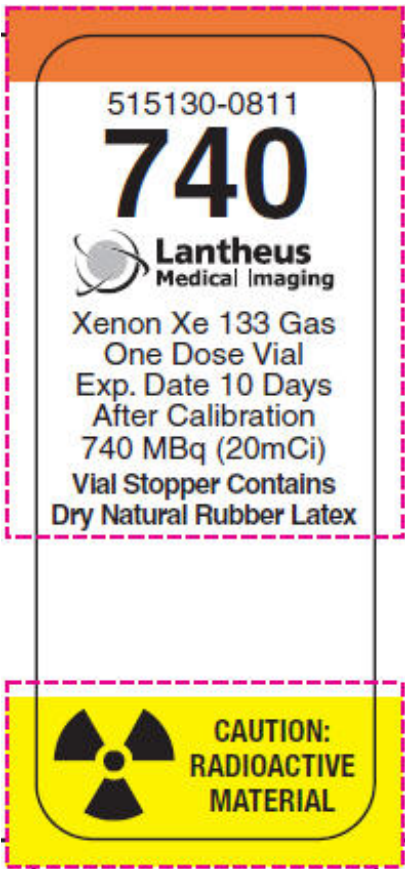
740

Lantheus
Medical Imaging

Xenon Xe 133 Gas
One Dose Vial
Exp. Date 10 Days
After Calibration
740 MBq (20mCi)

Vial Stopper Contains
Dry Natural Rubber Latex

CAUTION:
RADIOACTIVE
MATERIAL



XENON			
xenon xe-133 gas			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:11994-127
Route of Administration	RESPIRATORY (INHALATION)		
Active Ingredient/Active Moiety			

Ingredient Name		Basis of Strength	Strength	
XENON XE-133 (UNII: X3P9 A5HNYF) (XENON XE-133 - UNII:X3P9 A5HNYF)		XENON XE-133	10 mCi	
Inactive Ingredients				
Ingredient Name			Strength	
CARBON DIOXIDE (UNII: 142M471B3J)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11994-127-11	1 in 1 CAN	10/10/1974	
1		1 in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:11994-127-15	5 in 1 CAN	10/10/1974	
2		1 in 1 VIAL; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA017284	10/10/1974	

XENON				
xenon xe-133 gas				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:11994-128	
Route of Administration	RESPIRATORY (INHALATION)			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
XENON XE-133 (UNII: X3P9A5HNYF) (XENON XE-133 - UNII:X3P9A5HNYF)		XENON XE-133	20 mCi	
Inactive Ingredients				
Ingredient Name			Strength	
CARBON DIOXIDE (UNII: 142M471B3J)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11994-128-21	1 in 1 CAN	10/10/1974	
1		1 in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:11994-128-25	5 in 1 CAN	10/10/1974	
2		1 in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017284	10/10/1974	

Labeler - Lantheus Medical Imaging, Inc. (176786812)

Establishment

Name	Address	ID/FEI	Business Operations
Lantheus Medical Imaging, Inc.		176786812	RELABEL(11994-127, 11994-128) , REPACK(11994-127, 11994-128) , MANUFACTURE(11994-127, 11994-128)

Establishment

Name	Address	ID/FEI	Business Operations
Institut National des Radioelements		283049187	ANALYSIS(11994-127, 11994-128) , MANUFACTURE(11994-127, 11994-128)

Revised: 11/2020

Lantheus Medical Imaging, Inc.