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MPI XENON

Xe 133 Gas
Xenon Xe 133

Product Numbers: 5015, 5016

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DESCRIPTION: Medi-Physics Xenon Xe 133 Gas, Xenon Xe 133, is supplied as a gas for inhalation studies. MPI Xenon Xe 133 Gas is produced by fission of Uranium 235. It is chemically and physiologically related to elemental xenon, a non-radioactive monatomic gas which is physiologically inert except for anesthetic properties at high doses. No carrier added, trace amounts may be present at manufacture.

PHYSICAL CHARACTERISTICS: Xenon Xe 133 decays by beta emission with a physical half-life of 5.245 days'. The 81.0 keV gamma ray listed in Table I is useful for detection in imaging studies.

Table I Principal Radiation Emission Data

Radiation	Mean % / Disintegration	Mean Energy (keV)
Beta-2	99.30	100.6
Gamma-2	36.50	81.0
K int. con. electrons, gamma-2	53.30	45.0
L int. con. electrons, gamma-2	8.14	75.3
K X-rays, alpha	38.90	30.8
K X-rays, beta	9.10	35.0

Kocher, David C. "Radioactive Decay Data Tables," DOE/TIC-11026. p 138.1981

EXTERNAL RADIATION: The specific gamma ray constant for Xenon Xe133 is 0.51 R/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 lead is shown in Table 2. For example, the use of 0.20 cm of lead 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 and after the date of calibration are shown in Table 3.

Table 3 Physical Decay Chart Xenon Xe 133, half-life 5.245 Days

Days	Fraction Remaining	Days	Fraction Remaining
0*	1.000	8	0.347
1	0.876	9	0.304
2	0.768	10	0.267
3	0.673	11	0.234
4	0.509	12	0.205
5	0.516	13	0.179
6	0.453	14	0.157
7	0.397		

*Calibration day

CLINICAL PHARMACOLOGY: Xenon Xe 133 is a readily diffusable gas which is neither utilized nor produced by the body. It passes through cell membranes, freely exchanges between blood and tissue, and tends to concentrate more in body fat than in blood, plasma, water or protein solutions. In the concentrations recommended for diagnostic studies, it is physiologically inactive. Inhaled Xenon Xe 133 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: MPI Xenon Xe 133 Gas may be used in inhalation studies for the evaluation of pulmonary function, for lung imaging and the assessment of cerebral blood flow.

CONTRAINDICATIONS: None known

WARNINGS: The contents of the vial are radioactive. Adequate shielding of the preparation must be maintained at all times.

Xenon Xe 133 Gas delivery systems, ie., respirators or spirometers, and associated tubing assemblies must be leakproof to avoid loss of radioactivity into the laboratory 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 container for such unrecognized loss of radioactivity from the dose for administration may render the study non-diagnostic.

PRECAUTIONS:

General

Do not use after expiration (14 days after calibration time and date stated on label).

Exhaled Xenon Xe 133 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.

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 the patient consistent with proper patient management.

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, mutagenicity potential, or whether Xenon Xe 133 affects fertility in males or females.

Pregnancy Category C

Animal reproduction studies have not been conducted with Xenon Xe 133. It is also not known whether Xenon Xe 133 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Xenon Xe 133 should be given to a pregnant woman only if clearly needed. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, on 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 gas is excreted in human milk. Because many drugs are excreted in human milk and because of the potential of adverse reactions in nursing infants, formula feedings should be substituted for breast feeding.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS: No adverse reactions specifically attributable to the use of Xenon Xe 133 have been reported.

DOSAGE AND ADMINISTRATION The recommended adult (70kg) dosage range is:

Pulmonary function: 74-1110 MBq (2-30 mCi)/3 liters of air

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

Assay the activity of the Xenon Xe 133 prior to patient administration in a precalibrated ionization chamber.

Use contents of vial up to fourteen (14) days after calibration day. Thereafter, discard as per Disposal section.

RADIATION DOSIMETRY: The estimated absorbed radiation doses to an average adult (70 kg) for pulmonary perfusion and cerebral blood flow studies using 1110 MBq (30 mCi) of Xenon Xe 133 in 3 liters of air are shown in Table 4.

Table 4 Radiation

Organ	Absorbed Radiation Dose, Xenon Xe 133			
	Pulmonary		Cerebral	
	Perfusion		Blood Flow	
	mGy/1110 MBq	rads/30 mCi	MGy/1110 MBq	rads/30 mCi
	Effective $T_{1/2} = 2$ min		Effective $T_{1/2} = 5$ min	
Lung*	2.5	0.25	6.3	0.63
Brain	0.014	0.0014	0.035	0.0035
Whole Body	0.027	0.0027	0.068	0.0068

99% of activity is in lungs

Method of Calculation: A schema for Absorbed-Dose Calculations for Biologically Distributed Radionuclides, Supplement No 1. MIRSD Pamphlet No 1. *JNuclMed*.p 7,1968.

HOW SUPPLIED: MPI Xenon Xe 133 Gas is supplied as a gas in a 2.0 ml serum vials. Each vial contains 370 MBq (10 mCi) or 740 MBq (20 mCi) at calibration time.

The gas should be stored in its original container at room temperature. The vials should not be used after the expiration date (14 days after calibration) shown on the label.

NDC 017156-515-14 (10 mCi)

NDC 017156-516.17 (20 mCi)

DISPOSAL: Users should monitor the amount of radioactivity present prior to disposal of unit. Storage and/or disposal of radioactive materials should be in accordance with the conditions of NRC radioactive material license pursuant to 10 CFR, Part 20, or equivalent conditions pursuant to Agreement State Regulations, or with appropriate regulations of other government agencies authorized to license the use of radionuclides.

LICENSING: This radiopharmaceutical is approved for use by persons licensed by the U S Nuclear Regulatory Commission pursuant to sections 35.57 and 35.200 of 10 CFR 35 or under equivalent licenses of Agreement.

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