Hippuran® I 131 Injection

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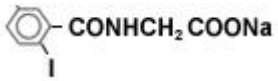
DESCRIPTION

Hippuran I 131 is a sterile, non-pyrogenic solution Containing iodohippurate sodium I 131 at a specific activity of 11.1 megabecquerels (0.3 millicurie) per milligram at the time of calibration. Each milliliter contains 0.833 milligram [9.25 megabecquerels (0.25 millicurie) iodohippurate sodium. The solution is preserved with 37.5% propylene glycol, 0.1% methylparaben and 0.03% propylparaben and stabilized with 0.015% sodium citrate and 0.005% edetate disodium. It may contain sodium hydroxide or hydrochloric acid for pH adjustment and trace quantities of sodium acetate. The pH is between 7.0 and 8.5. The amount of free (unbound) iodine I 131 does not exceed 3%. Iodohippurate sodium I 131 has the following chemical structure:



PHYSICAL CHARACTERISTICS

Iodine I 131 decays by beta and associated gamma emissions with a physical half-life of 8.04 days.[1] The principal beta emissions and gamma photons are listed in Table 1.

Table 1. Principal Radiation Emission Data[1]

Radiation	Mean %/ Disintegration	Energy (keV)
Beta-1	2.12	69.4 avg.
Beta-3	7.36	96.6 Avg.
Beta-4	89.3	191.6 Avg.
Gamma-7	6.05	284.3
Gamma-14	81.2	364.5
Gamma-17	7.26	637.0

EXTERNAL RADIATION

The specific gamma ray constant for iodine I 131 is 2.27 R/hr-mCi at 1 cm. The first half-value thickness of lead (Pb) for iodine I 131 is 0.24 cm. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of Pb is shown in Table 2. For example, the use of 4.6 cm of Pb will decrease the external radiation exposure by a factor of about 1,000.

Table 2. Radiation Attenuation by Lead Shielding[2]

Shield Thickness (Pb), cm	Coefficient of Attenuation
0.24	0.5
0.95	10^{-1}
2.6	10^{-2}
4.6	10^{-3}
6.5	10^{-4}

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

Table 3. Physical Decay Chart; Iodine I 131,Half-Life 8.04 Days

Days	Fraction Remaining	Days	Fraction Remaining
0*	1.000	16	0.252
1	0.917	17	0.231
2	0.842	18	0.212
3	0.772	19	0.194
4	0.708	20	0.178
5	0.650	21	0.164
6	0.596	22	0.150
7	0.547	23	0.138
8	0.502	24	0.126
9	.460	25	0.116
10	0.422	26	0.106
11	0.387	27	0.098
12	0.355	28	0.089
13	0.326	29	0.082
14	0.299	30	0.075
15	0.274		

*Calibration Day

CLINICAL PHARMACOLOGY

Following intravenous injection of Hippuran I 131 the appearance, concentration and excretion of the tracer in the kidney can be monitored. Tubular cell secretion is primarily displayed. An index of renal vascular competence and renal evacuation may also be estimated.

INDICATIONS AND USAGE

Hippuran I 131 Injection is a diagnostic aid in determining renal function, renal blood flow, ar urinary tract obstruction, and a renal imaging agent.

CONTRAINDICATIONS

None known.

WARNINGS

This drug may contain up to 3% free iodine I 131. saturated solution of potassium iodide or a dose of 1 to 20 drops of Lugol's solution should be administered prior to and following the examination to decrease thyroid accumulation of iodine I 131.

PRECAUTIONS

General

As in the use of other radioactive material, care should be taken to insure minimum radiation exposure to the patient, consistent with the proper patient management, and to insure minimum radiatic exposure to occupational workers.

The vial contents are sterile. It is essential that the user follow the directions carefully and adhere to strict aseptic procedures.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No long-term animal studies have been performed to evaluate the carcinogenic or mutagenic potential, or whether this drug affects fertility in males or females.

Pregnancy Category C

Animal reproduction studies have not been conducted with iodohippurate sodium I 131. It is also not known whether iodohippurate sodium I 131 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Iodohippurate sodium I 131 should be given to a pregnant woman only if clearly needed. Ideally, examinations using radiopharmaceuticals, especially those elective in nature, of a woman of childbearing capability should be performed during the first few (approximately 10) days following the onset of menses.

Nursing Mothers

Iodine I131 is excreted in human milk during lactation, therefore, formula feedings should be substituted for breast feedings.

Pediatric Use

Safety and effectiveness in pediatric patients has not been established.
Radiopharmaceuticals should be used only by physicians who are qualified by specific training in the safe use and handling or radionuclides produced by nuclear reactor or particle accelerator and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

ADVERSE REACTIONS

As with all organic iodine-containing compounds, the possibility of allergic type reactions must be kept in mind. Nausea, vomiting and fainting have been reported in conjunction with the administration of Hippuran I 131 Injection .

DOSAGE AND ADMINISTRATION

The suggested dose range employed in the average patient (70 kg) for renal function studies is up to 1.295 megabecquerels (35 microcuries) administered intravenously [18.5 kilobecquerels (0.5 microcurie) per kilogram body weight].

When renal imaging is required, the dose for the average patient (70 kg) is up to 12.95 megabecquerels (350 microcuries) [111 to 185 kilobecquerels (3 to 5 microcuries) per kilogram body weight].

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

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Instructions for the Handling of Iodohippurate Sodium I 131

1. Waterproof gloves should be used during the entire handling and administration procedure.
2. Using proper shielding, the vial containing the Iodohippurate Sodium I 131 should be visually inspected to insure that it is free of particulate matter and discoloration prior to use.
3. Maintain adequate shielding during the life of the product and use a sterile, shielded syringe for withdrawing and injecting the preparation.

RADIATION DOSIMETRY

The estimated radiation doses[3] to an average patient (70 kg) from an intravenous dose of 12.95 megabecquerels (350 microcuries) of Iodohippurate Sodium I 131 are shown in Table 4. The values are based on a completely blocked thyroid and a biphasic excretion curve. After administration of the drug about 62% of the activity has an effective half-life of 7.4 minutes, and 38% has an effective half-life of 37 minutes .

Table 4. Absorbed Radiation Doses

Tissue	Absorbed radiation doses for 12.95 megabecquerels (350 microcuries)	
	mGy	rads
Thyroid	0.39*	0.039*
Kidneys	0.28	0.028
Bladder Wall	20.0	2.000
Testes	0.39	0.039
Ovaries	0.46	0.046
Total Body	0.39	0.039

*This product may contain up to 3% free iodine I 131. If the thyroid is not blocked with saturated potassium iodide or Lugol's solution, and the thyroid uptake is 25%, the absorbed radiation dose for the thyroid would be 14 rads. This value will decrease proportionately if less than 3% free iodine I131 is present, or if the uptake is less than 25%. Conversely, it will increase if the uptake is greater than 25%.

HOW SUPPLIED

Catalog Number 115.

Hippuran I 131 Injection (Iodohippurate Sodium I131 Injection). A sterile, non-pyrogenic solution containing 37.5% propylene glycol. 0 1% methylparaben, and 0.03% propylparaben as preservatives: 0.015% sodium citrate and 0.005% edetate disodium as stabilizers. May contain sodium hydroxide or hydrochloric acid for pH adjustment and trace quantities of sodium acetate. Hippuran I 131 Injection is available in vials containing 37 megabecquerels

(1 millicurie) with a concentration of 9.25 megabecquerels (0.25 millicurie) per milliliter and specific activity of 11.1 megabecquerels (0.3 millicurie) per milligram as of time of calibration.

Hippuran I131 Injection should not be used beyond the expiration date stated on the label.

STORAGE AND HANDLING

Store at room temperature (Below 86°F/30°C)

Storage and disposal of Hippuran I 131 Injection should be controlled in a manner that is in compliance with the appropriate regulations of the government agency authorized to license the use of this radionuclide.

PERFORMING THE RENOGRAM

Patient Preparation

The state of hydration of the patient will influence the excretion of the tracer and the shape of the renogram curve. In dehydrated patients, the time required to reach the peak radioactivity level in the kidney is prolonged, and the second and third phases of the renogram are flatter. False diflerences in rates of tracer excretion may occur due to increased pooling of highly concentrated urine in slight non-pathologic variations of the ureteral outlets In the hydrated patient, good second phase comparisons are obtained, but differences in rates of excretion may be obscured.

Positioning

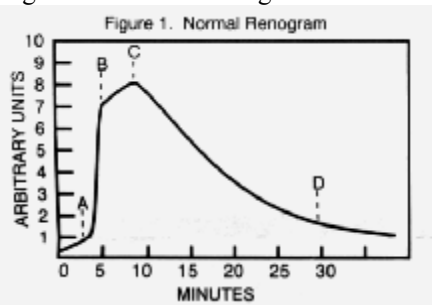
The patient is generally placed in a sitting position. The prone or supine position may also be employed if the patient is unable to maintain a steady sitting position. A gamma camera interfaced with a computer is placed directly over the kidneys at right angles to the back.

Interpretation of Results

The renogram provides diagnostic information relating to two basic problems: those affecting kidney function or blood supply and those obstructing urinary tract flow

Figure 1 is a schematic representation of a normal renogram. The three segments of the curve were originally called the vascular, tubular and excretion phases. Dore et al [4] renamed these segments as: 1) tracer appearance, 2) blood flow, and 3) drainage.

Figure 1. Normal Renogram



The first phase, segment AB, represents the initial appearance of the radioactivity under the detector. This appearance is noted a few seconds following the injection and lasts about 30 seconds. The second phase, segment BC, is the uptake of the tracer by the kidney. The shape of this portion of the curve is affected by changes in the renal blood flow and the cellular function of the kidney.

This slowly rising second phase of the renogram usually lasts for about 2 to 5 minutes Segment CD, or the third phase, represents the removal of the tracer from the kidney pelvis. The state of hydration, capacity of the renal pelvis, anatomic relations between the pelvis and the ureter, and any existing pathologic abnormalities influence the shape of this curve. The tracing is normally continued for about 30 minutes, although sufficient information may be obtained after about 15 minutes.

Illustrated in Figures 2 and 3 are examples of abnormal renograms. Figure 2 is a renogram showing a moderate decrease in function or blood supply in the right kidney; Figure 3 shows an acute unilateral (right) urinary tract obstruction

Abnormal Renograms

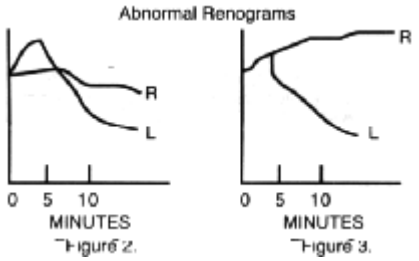


Figure 2. Figure 3.

The U .S. Nuclear Regulatory Commission has approved distribution of this radiopharmaceutical to persons licensed to use byproduct material listed in Sections 35.100, and to persons who hold an equivalent license issued by an Agreement State.

[1]Kocher, David C., "Radioactive Decay Data Tables," DOE/TIC 11026, page 133 (1981).

[2] Data supplied by Oak Ridge Associated Universities, Radiopharmaceutical Internal Dose Information Center, Oak Ridge, TN, 1987.

[3] 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.

[4]Dore, E.K, Taplin, G.V. and Johnson, D.E., Current Interpretation of the Sodium lodohippurate I 131 Renocystogram, J.A.M.A. 185:925, September 21, 1983.

Revised 7/95
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