SUMMARY OF PRODUCT CHARACTERISTICS

TECHNETIUM Tc-99M GENERATOR

MOLYBDATE (CONTAINING MO-99)
Radio-Pharma Generator
For Intravenous Use

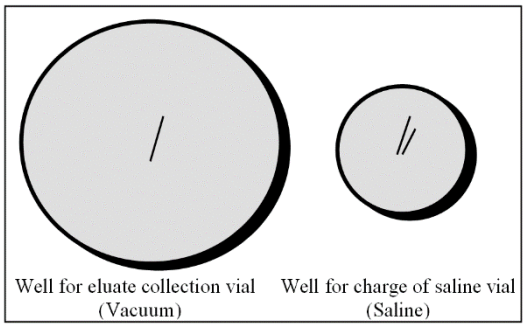
To be used in Diagnostic institutes only

DESCRIPTION:

Sodium Pertechnetate Tc 99m Injection, as eluted according to the elution instructions with Soreq Radiopharmaceutical's Technetium Tc99m Generator, is in Sodium Chloride 0.9% as a sterile, non-pyrogenic, diagnostic radiopharmaceutical suitable for intravenous injection, oral administration, and direct instillation. The pH is 4.5-7.5. The eluate should be clear, colorless, and free from visible foreign material. Each eluate of the Technetium Tc 99m Generator should not contain more than 0.0056MBq (0.15 microcuries) of Molybdenum Mo99 per 37MBq (1 millicurie) of Technetium Tc 99m per administered dose at the time of administration, and not more than 10 micro-grams of aluminum per milliliter of the Technetium Tc 99m Generator eluate, both of which are recommended to be determined by the user before administration. Since the eluate does not contain an antimicrobial agent, it should not be used later than12 hours after the elution.

Soreq Radiopharmaceutical's Technetium Tc 99m Generator consists of a column containing fission produced Molybdenum Mo99 adsorbed on alumina. The terminally sterilized and sealed column is enclosed in a lead shield; the shield and other components are sealed in cylindrical plastic container with an attached handle.

Built into the top surface are two recessed wells as it is shown in the sketch.



Needles protruding from these two wells accommodate supplied sterile eluant charge vials and sterile eluate collection vials. The eluting solvent consist of 5ml or 15ml Sodium Chloride 0.9% solution, in prepacked septum-sealed vials.

The eluate collection vial is evacuated sterile and non-pyrogenic.

During and subsequent to elution, the eluate collection vial should be kept in a radiation shield. The Generator is shipped with a sterile needle seal over the charge needle and a vented needle cover over the collect needle.

PHYSICAL CHARACTERISTICS

Technetium Tc 99m decays by isomeric transition with physical half-life of 6.02 hours. [1]Photons that are useful for imaging studies are listed in Table 1.

Table 1. Principal Radiation Emission Data - Technetium Tc 99m

Radiation	Mean %/Disintegration	Mean Energy (keV)
Gamma-2	89.07	140.5

[1]Kocher, David C., "Radioactive Decay Data Tables," DOE/TIC-11026, 108 (1981)

EXTERNAL RADIATION

The specific gamma ray constant for Technetium Tc 99m is 5.4 micro-coulombs/Kg-MBq-hr (0.78 R/mCi-hr) at 1cm. The first half-value thickness is 0.017cm of lead (Pb). The use of a 0.25cm thick standard radiation elution lead shield will attenuate the radiation emitted by factor of about 1000. A range of values for the relative attenuation of the radiation emitted by this radionuclide that results from interposition of various thicknesses of lead is shown in Table 2.

The Eluting Shield has a wall thickness of 8mm, and reduces transmitted Technetium Tc 99m radiation essentially to zero.

Note: Because the generator is well contained and essentially dries, there is little likelihood of contamination due to damage in transit. The most probable source of leakage resulting from damage in transit is the no radioactive eluant charge vial.

Table 2. Radiation Attenuation of Technetium Tc 99m by Lead Shielding

Shield Thickness lead (Pb) cm Attenuation	Coefficient of
0.017	0.5
0.08	10^{-1}
0.16	10^{-2}
0.25	10^{-3}
0.33	10^{-4}

Molybdenum Mo99 decays to Technetium Tc 99m with a Molybdenum Mo99 half-life of 66 hours. The physical decay characteristics of Molybdenum Mo99 are such that only 86.8% of the decaying Molybdenum Mo99 atoms form Technetium Tc 99m. This means that only 78% of the activity remains after 24 hours; 60% remains after 48 hours (Table 3).

Since the Molybdenum Mo99 is constantly decaying to fresh Technetium Tc 99m, it is possible to elute the generator at any time; however the amount of

Technetium Tc 99m available will depend on the interval from the last elution: approximately 47% of maximum Technetium Tc 99m is reached after 6 hours and 95% after 24 hours (Table 4).

In the elution fractions that remain, the correction for physical decay of Tc 99m, at selected intervals of time are shown in Table 5.

CLINICAL PHARMACOLOGY: The pertechnetate ion distributes in the body similarly to the iodide ion but is not organified when trapped in the thyroid gland.
Pertechnetate tends to accumulate in intracranial lesions with excessive neovascularity or an altered blood-brain barrier. It also concentrates in the choroids' plexus, thyroid gland, salivary glands and stomach. However, in contrast to the iodide ion, the pertechnetate ion is released unchanged from the thyroid gland.
After intravascular administration it remains in the circulatory system for sufficient time to permit blood pool, organ perfusion, and major vessel studies. It gradually equilibrates with the extra cellular space. A fraction is promptly excreted via the kidneys.

WARNINGS: Radiation risks associated with the use of Sodium Pertechnetate Tc 99m Injection are greater in children than in adults and, in general, the younger the child, the greater the risk owing to greater absorbed radiation doses and longer life-expectancy. These greater risks should be taken firmly into account in all benefit-risk assessments involving children.

INDICATIONS AND USAGE:
Diagnostic agent for IV injection producer of Tc-99 for imaging of different organs.
Sodium Pertechnetate Tc 99m Injection is used IN ADULTS as an agent for:
Brain Imaging (including cerebral radionuclide angiography)
Thyroid Imaging
Salivary Gland Imaging
Placenta Localization
Blood Pool Imaging (including radionuclide angiography)
Urinary Bladder Imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux.
Nasolacrimal Drainage System Imaging

Sodium Pertechnetate Tc 99m Injection is used IN CHILDREN as an agent for:
Brain Imaging (including cerebral radionuclide angiography)
Thyroid Imaging
Blood Pool Imaging
Urinary Bladder Imaging (direct isotopic cystography) for the detection of vesico-ureteral reflux.

Table 3-Decay factor for Mo-99 (D)

time (hr)	D	time (hr)	D	time (hr)	D	time (hr)	D	time (hr)	D	time (hr)	D
0	1.000	24	0.778	48	0.605	72	0.470	120	0.285	168	0.172
1	0.990	25	0.770	49	0.599	74	0.461	122	0.279	172	0.165
2	0.979	26	0.762	50	0.592	76	0.451	124	0.273	176	0.158
3	0.969	27	0.754	51	0.586	78	0.442	126	0.267	180	0.152
4	0.959	28	0.746	52	0.580	80	0.433	128	0.262	184	0.146
5	0.949	29	0.738	53	0.574	82	0.424	130	0.256	188	0.140
6	0.939	30	0.730	54	0.568	84	0.415	132	0.251		
7	0.929	31	0.723	55	0.562	86	0.406	134	0.246	192	0.134
8	0.920	32	0.715	56	0.556	88	0.398	136	0.241	196	0.128
9	0.910	33	0.708	57	0.550	90	0.390	138	0.236	200	0.123
10	0.901	34	0.700	58	0.545	92	0.382	140	0.231	204	0.118
11	0.891	35	0.693	59	0.539	94	0.374	142	0.226	208	0.113
12	0.882	36	0.686	60	0.533					212	0.109
13	0.873	37	0.679	61	0.528	96	0.366	144	0.221		
14	0.864	38	0.672	62	0.522	98	0.358	146	0.217	216	0.104
15	0.857	39	0.665	63	0.517	100	0.351	148	0.212	220	0.100
16	0.846	40	0.658	64	0.512	102	0.344	150	0.208	224	0.096
17	0.837	41	0.651	65	0.506	104	0.337	152	0.204	228	0.092
18	0.828	42	0.644	66	0.501	106	0.330	154	0.200	232	0.088
19	0.820	43	0.637	67	0.496	108	0.323	156	0.195	236	0.084
20	0.811	44	0.631	68	0.491	110	0.316	158	0.191		
21	0.803	45	0.624	69	0.486	112	0.309	160	0.187	240	0.08
22	0.794	46	0.618	70	0.480	114	0.303	162	0.184	252	0.071
23	0.786	47	0.611	71	0.475	116	0.297	164	0.180		
24	0.778	48	0.605	72	0.470	118	0.291	166	0.176	264	0.063

Table 4-Growth factor for Tc-99m (G)

time (hr)	G	time (hr)	G	time (hr)	G	time (hr)	G
0 00	0.000	6 00	0.443	12 00	0.679	24	0.872
15	0.024	15	0.450	30	0.693	25	0.880
30	0.048	30	0.468	13 00	0.706	26	0.887
45	0.072	45	0.481	30	0.718	27	0.893
1 00	0.094	7 00	0.493	14 00	0.723	28	0.898
15	0.116	15	0.505	30	0.741	29	0.903
30	0.138	30	0.516	15 00	0.752	30	0.908
45	0.159	45	0.527	30	0.762	31	0.912
2 00	0.179	8 00	0.538	16 00	0.771	32	0.916
15	0.199	15	0.549	30	0.780	33	0.919
30	0.219	30	0.559	17 00	0.789	34	0.922
45	0.237	45	0.569	30	0.797	36	0.927
3 00	0.256	9 00	0.579	18 00	0.805	38	0.931
15	0.274	15	0.589	30	0.812	40	0.935
30	0.291	30	0.598	19 00	0.819	42	0.937
45	0.308	45	0.607	30	0.826	44	0.939
4 00	0.325	10 00	0.616	20 00	0.832	46	0.941
15	0.341	15	0.624	30	0.838	48	0.943
30	0.357	30	0.633	21 00	0.844	52	0.945
45	0.372	45	0.641	30	0.849	56	0.946
5 00	0.387	11 00	0.649	22 00	0.854	60	0.947
15	0.401	15	0.657	30	0.859	64	0.948
30	0.415	30	0.664	23 00	0.864	68	0.948
45	0.429	45	0.672	30	0.868	72	0.948

Table 5 - Decay factor for Tc-99m

time (hr)		time (hr)		time (hr)		time (hr)		time (hr)		time (hr)	
0 00	1.000	2 00	0.794	5 00	0.562	8 00	0.398	14	0.199	26	0.050

10	0.981	15	0.772	15	0.546	30	0.376	15	0.178	28	0.040
20	0.962	30	0.750	30	0.531	9 00	0.355	16	0.158	30	0.032
30	0.944	45	0.729	45	0.516	30	0.335	17	0.141	32	0.025
40	0.926	3 00	0.708	6 00	0.501	10 00	0.316	18	0.126	34	0.020
50	0.908	15	0.688	15	0.487	30	0.298	19	0.112	36	0.016
1 00	0.891	30	0.668	30	0.473	11 00	0.282	20	0.100	38	0.013
10	0.874	45	0.649	45	0.460	30	0.266	21	0.089	40	0.010
20	0.858	4 00	0.631	7 00	0.447	12 00	0.251	22	0.079	42	0.008
30	0.841	15	0.613	15	0.434	30	0.237	23	0.071	44	0.006
40	0.825	30	0.596	30	0.422	13 00	0.224	24	0.063	46	0.005
50	0.810	45	0.579	45	0.410	30	0.211			48	0.004

CONTRAINDICATIONS: None known**.**

PRECAUTIONS:

General

Sodium Pertechnetate Tc 99m Injection, as other radioactive drugs must be handled with care. Appropriate safety measures should be taken to minimize radiation exposure to both the clinical personnel and the patients.

Radiopharmaceuticals should be used only by physician who are qualified by training and experience in the safe handing 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 animal studies have been performed to evaluate carcinogenic potential or whether Sodium Pertechnetate Tc 99m affects fertility in males or females.

Pregnancy Category C

Animal reproductive studies have not been conducted with Sodium Pertechnetate Tc 99m. It is also not known whether Sodium Pertechnetate Tc 99m can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Pertechnetate Tc 99m Injection 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

Sodium Pertechnetate Tc 99m is excreted in human milk during lactation; therefore formula feedings should be substituted for breast feeding.

This radiopharmaceutical preparation should not be administered to pregnant or lactating women unless expected benefits to be gained outweigh the potential risks.

Pediatric use

See INDICATIONS and DOSAGE AND ADMINISTRATION sections. Also see the description of additional risks under WARNINGS.

DIAGNOSTIC INTERFERENCE

The following have been selected on the basis of their potential clinical significance (possible effect in parentheses where appropriate) – not necessarily inclusive.

With results of brain imaging

Due to other medications

Antacids: aluminum-containing

(Prior administration of aluminum-containing antacids may decrease uptake of sodium Pertechnetate Tc99m in brain lesions)

Antineoplastics: especially intrathecally- administered

(Chemotherapeutic neurotoxicity may result in patchy increased brain uptake or localization in ventricles or meninges).

Corticosteroids, glucosteroid

(Concurrent use may decrease brain tumor or abscess uptake of sodium Pertechnetate Tc99m because of reduced pertumor edema caused by large doses of the steroid)

Technetium Tc99m pyrophosphate

(brain scan may give either false-positive or false-negative results when performed after a bone scan using technetium Tc99m pyrophosphate that contains stannous ions; to avoid false results, brain scan may be performed prior to bone scan or with a brain imaging agent other than sodium Pertechnetate Tc99m)

With results of thyroid uptake tests and thyroid imaging

Due to other medications

Antacids, aluminum-containing or Amiodarone or Ant thyroid agents – (thioamide derivatives or aromatic preparation or Contrast media, iodinated or Corticosteroids or Goitrogenic foods (e.g. cabbage, turnips) or

Iodine-containing foods or Iodine-containing preparations or Iodine-contaminated bromides or Iodine, stable or

Monovalent anions (e.g. perchlorate, thiocyanate) or Pyrazolone derivatives, such as oxyphenbutazone and phnylbutazone or Salicylates, chronic administration of, or Salt, iodized, excessive intake of or Thiopental or

Thyroid blocking agents, such as strong iodine solution, potassiumiodide, or potassium perchlorate or

Thyroid preparations, natural or synthetic (may decrease thyroidal uptake of Pertechnetate ion)

(a rebound affect may occur following the sudden withdrawal of antithyroid preparations, resulting in a period of up to 5 days of very high thyroidal uptake)(a rebound effect may also occur when discontinuing salicylate therapy, resulting in a period of 3 to 10 days of increased thyroidal uptake)

With results of salivary glade imaging

Due to other medications

Perchlorate or Sodium iodide I131, therapeutic (may decrease salivary uptake of Pertechnetate ion)

With results of gastric mucosa imaging

Due to other medications

Antacids, aluminum-containing (prior administration of aluminum-containing antacids may decrease stomach uptake and urinary extraction of sodium Pertechnetate Tc99m and thus interfere with Meckel's diverticula evaluation)

Perchlorate

(May decrease gastric uptake of sodium Pertechnetate Tc99m if given prior to imaging of Meckel's diverticulum)

With results of cardiac blood pool imaging and diagnosis of gastro-intestinal bleeding using Tc99m-labeled red blood cells

Due to other medications

Digoxin or Doxorubicin or Heparin sodium or Hydralazine or Methyldopa or Prazosin or Propranolol or Quinidine or

Radiopaque agents, water-soluble organic iodides, with intravascular administration (these medications may impair blood pool imaging by decreasing the labeling of red blood cells)

Due to medical problems or conditions

Goiter, toxic diffuse or Hyperthyroidism (thyroid uptake may be increased)

Lupus erythernatosus (Labeling of red blood cells may be decreased)

Trancsfusion-induced reaction (Labeling efficiency may be decreased because of red blood cell antibody formation)

ADVERSE REACTIONS: Allergic reactions including anaphylaxis have been reported infrequently following the administration of Sodium Pertechnetate Tc 99m Injection.

Reporting of suspected adverse reactions

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form (https://sideeffects.health.gov.il).

DOSAGE AND ADMINISTRATION: Sodium Pertechnetate Tc 99m Injection is usually administered by intravenous injection, but can also be given orally. When Sodium Pertechnetate is given orally, fasting is recommended for at least 6 hours before and 2 hours after administration. For imaging the urinary bladder and ureters (direct isotopic cystography), the Sodium Pertechnetate Tc 99m Injection is administered by direct instillation aseptically into the bladder via an urethral catheter. The dosage employed varies with each diagnostic procedure. Prior to administration of Sodium Pertechnetate Tc99m for brain or blood pool imaging, up to 1 gram of pharmaceutical grade potassium perchlorate may be given orally to help block the uptake of Tc99m into thyroid gland, salivary glands, choroid plexus and gastro mucosa. This is especially important in children receiving sodium Pertechnetate Tc99m for brain or blood pool imaging, in order to reduce the absorbed radiation dose to the thyroid gland.

The suggested dose range employed for various diagnostic indications in the average ADULT PATIENT (70kg) is:

Vesico-ureteral Imaging	18.5 to 37MBq (0.5 to 1mCi)
Brain Imaging	370 to 740MBq (10 to 20mCi)
Thyroid Gland Imaging	37 to 370MBq (1 to 10mCi)
Salivary Gland Imaging	37 to 185MBq (1 to 5mCi)
Placenta Localization	37 to 111MBq (1 to 3mCi)
Blood Pool Imaging	370 to 1110MBq (10 to 30mCi)

The recommended dosage range in PEDIATRIC PATIENTS is:

Vesico-ureteral Imaging	18.5 to 37MBq (0.5 to 1mCi)
Brain Imaging	5.18 to 10.36MBq (140 to 280μCi)/kg body weight
Thyroid Gland Imaging	2.22 to 2.29MBq (60 to 80μCi) /kg body weight
Blood pool Imaging	5.18 to 10.36MBq (140 to 280μCi)/kg body weight

A minimum dose of 111 to 185MBq (3 to 5mCi) should be employed if radionuclide angiography is performed as part of the blood pool or brain imaging procedure.
The patient dose should be measured by a suitable radioactivity calibration system immediately prior to its administration.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
The solution to be administered as the patient dose should be crystal clear and contain no particulate matter. Do not use an eluate of the Technetium Tc 99m Generator later than 12 hours after elution.

RADIATION DOSIMETRY
The estimated absorbed radiation doses[2] to an average ADULT patient (70kg) from an intravenous injection of a maximum dose of 1110MBq (30 mCi) of Sodium Pertechnetate Tc 99m Injection distributed uniformly in the total body of subject not pretreated with blocking agents such as pharmaceutical grade Potassium Perchlorate are shown in Table 6.

Table 6. Absorbed Radiation Doses (Adult of 70 kg)

Tissue	Absorbed Radiation
Stomach	0.014 mGy/MBq (0.051 rad/mCi)
Thyroid	0.035 mGy/MBq (0.130 rad/mCi)

Bladder	0.023 mGy/MBq (0.085 rad/mCi)
Ovaries	0.008 mGy/MBq (0.030 rad/mCi)
Testes	0.002 mGy/MBq (0.009 rad/mCi)
Bone Marrow	0.005 mGy/MBq (0.017 rad/mCi)
Whole Body	0.003 mGy/MBq (0.011 rad/mCi)

For placenta localization studies, when a maximum of 111MBq (3 millicuries) is used, it is assumed to be uniformly equilibrated between maternal and fetal tissues.

Absorbed Radiation Doses from Sodium Pertechnetate Tc 99m Injection when administered to pediatric patients are shown in Table 7.

Table 7. Absorbed Radiation Doses (Pediatric)

Tissue	Absorbed Radiation Doses (rads/1mCi)
Thyroid (without Perchlorate)	4.6
Thyroid (with Perchlorate)	0.97
Large Bowel (with Perchlorate)	1.9
Testes	0.10
Ovaries	0.22
Whole-Body	0.15

[2] Modified from: Summary of Current Radiation Dose Estimates to Normal Humans from 99m-Tc as Sodium Pertechnetate. MIRD Dose Estimates Report No. 8. J. Nucl. Med. 17(1): 74-77, 1976.
[3] Conway, JJ, et al: Direct and Indirect radionuclide cystography. J. Urol. 113:689-693 May 1975.

HOW SUPPLIED: Soreq Radiopharmaceutical's, Technetium Tc 99m Generator is available at the various Mo 99 radioactivity amounts, on the calibration date (as specified on the product lot identification label affixed to the generator), from 150mCi (5.55 GBq) and up to 8000mCi (296GBq), as per client request.

Each generator is supplied with the following additional components:

1 Seal Vial for the Collection Needle (placed in generator dust cover)
18 Eluate Collection Vials (VACUUM)
6 5cc Saline Vials
6 15cc Saline Vials
1 Package Insert
10 Radiation Labels (for Collection Vials)
10 Radiation Labels (for Eluting Shield)

One Eluting Shield is provided with every first order of a Soreq Radiopharmaceutical's, Technetium Tc 99m Generator.

Extra amounts of all components may be obtained at request.

STORAGE: At or below room temperature. Under 25°C.

EXPIRATION:
The expiration date of the Technetium Tc99m Generator is a maximum of 24 days after calibration.

The expiration time of the Sodium Pertechnetate Tc 99m Injection is not later than 12 hours after elution. (If the eluate is to be used to reconstitute a kit for the preparation of a Technetium Tc 99m radiopharmaceutical, the kit should not be used after 12 hours from time of Generator elution or after six hours the time of reconstitution of the kit).

ELUTION INSTRUCTION

1. Waterproof gloves should be worn during elution.
2. Remove dust (clear plastic) cover of generator which contains the sterile collect needle seal vial with bacteriostat.
3. Perform all subsequent operations aseptically.
4. Remove silicone needle seal from eluant charge well. **Discard as radioactive** waste.
5. Remove flip-off seal and swab septum of **5ml or 15 ml saline vial** with a bactericide (such as 70% isopropyl alcohol), allow drying, and inserting the vial into charge well. Vial should be firmly inserted to assure puncture of septum.
6. Open Elution Shield base and insert an eluate collection vial **(vacuum)** from which the flip-off seal has been removed. Screw base back on securely. Swab the exposed vial septum with a bactericide.
7. Remove vented needle cover from collect well. **Discard as radioactive waste**.
8. Insert shielded eluate collection vial in the collect well. Elution should commence within 30 seconds and can be visually checked by the appearance of bubbles in the eluant charge vial. **

**NOTE: if bubbles do not appear in the eluant charge vial within 30 seconds, either one of the vials has not been properly placed on its needle or the eluate vial has no vacuum. Remove the eluate collection vial to prevent vacuum loss; then remove and reinsert the charge vial. Reinsert the eluate collection vial and if elution does not commence, use a second shielded collection vial.

9. To assure proper yield and functioning, elution must proceed to completion as evidenced by emptying of charge vial. Allow generator to elute for at least 3 minutes after the charge has been drained, or for a total of 6 minutes.
10. After elution has been completed, remove the Elution Shield containing the collection vial.
    Insert over the collect needle another eluate collection vial, from which the flip-off seal has been aseptically removed. The eluant vial is sterile and should stay in place until the next elution, functioning as a seal for the needle within the charge well. Upon initiating the next elution, discard the empty eluant vial as radioactive waste.
11. Fill out and attach the appropriate radioactivity labels to the elution shield containing the filled eluate collection vial. Do not use an eluate of the Technetium Tc 99m Generator later than 12 hours of elution.
12. Use a shielded syringe when introducing the Sodium Pertechnetate Tc 99m solution into mixing vials.
13. Maintain adequate shielding during the life of the radioactive preparation by using a lead vial shield and cover, and use a shielded syringe for withdrawing and injecting the preparation.

ASSAY INSTRUCTIONS FOR THE

TECHNETIUM Tc 99m GENERATOR ELUATE

The Technetium Tc 99m Generator Eluate may be assayed using an ionization chamber dose calibrator. The manufacturer's instructions for operation of the dose calibrator should be followed for measurement of Technetium Tc 99m and Molybdenum Mo99 activity in the generator eluate. The Molybdenum 99/Technetium 99m ratio should be determined at the time of elution prior to administration, and from that ratio, the expiration time (up to 12 hours) of the eluate mathematically determined. Each eluate should meet or exceed the purity requirements of the current United States Pharmacopoeia; that is, not more than 0.0056MBq (0.15 microcurie) of Molybdenum 99 per 37MBq (1 millicurie) of Technetium 99m per administered dose at the time of administration.

MANUFACTURER

ISORAD LTD

NAHAL SOREQ,

YAVNE 81800, ISRAEL

REGISTRATION HOLDER

ISORAD LTD

NAHAL SOREQ,

YAVNE 81800, ISRAEL

MARKETING AUTHORISATION NUMBER

056-71-22261-00

The content of this leaflet was approved by the Ministry of Health in Jan 2014 and updated according to the guidelines of the Ministry of Health in Apr 2023