PACKAGE LEAFLET: INFORMATION FOR THE USER

MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR, 5-50 GBq, radionuclide generator
For intravenous or as eye drop

Active Ingredient:
Mother nuclide:
Sodium Molybdate ($Na^{99}MoO_4$) 5-50 GBq / Generator
(Mo-99 radioactivity in the calibration day)

Daughter nuclide:
Sodium (^{99m}) pertechnetate (Obtained from ^{99}Mo / ^{99m}Tc generator system)

Excipients:
Aluminum oxide, molybdenum trioxide, sodium hydroxide, hydrochloric acid, hydrogen peroxide and isotonic sodium chloride solution.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you, do not pass it on to others.*
- *Please strictly follow the instructions given in this leaflet. Do not ever use higher or lower dose than the dosage prescribed for and recommended to you.*
- *Tell your doctor that you are using this medicine when you go to the hospital or doctor during your medication.*

In this leaflet:

1. What is MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR and what it is used for?

This medicine is a radiopharmaceutical product for diagnostic use only.

MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR is a system used to obtain sodium pertechnetate (^{99m}Tc) solution used for diagnosis purposes. Sodium pertechnetate (^{99m}Tc) is radioactive isotope of technetium element and has a very short half-life. For this reason, it is obtained in the administration centers through a system called Generator.
The solution from the generator contains a small amount of radioactivity. Solution might be administered directly to you or used for labelling of various compounds in order to investigate your disease.

This medicine is used through intravenous injection or by dropping into eyes.

MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR is used for evaluation of thyroid gland, salivary glands, gastrointestinal tract and tear ducts of the eyes.

The doctor may use this medicine for other purposes. If you have any questions ask your doctor.

The use of MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR does involve exposure to small amounts of radioactivity. Your doctor and the Nuclear medicine doctor have considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical overcomes the risk due to radiation.

2. Before MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR is administered

MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR must never be used
If you are allergic to sodium pertechnetate ^{99m}Tc active substance in the solution or to any of the other ingredients or to any of the components of the labelled radiopharmaceutical.

If you are using a ^{99m}Tc labeled pharmaceutical preparation, you should read information on contraindications in the SmPC and PIL of the kit for radiopharmaceutical preparation.

Take special care with MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR
Talk to your Nuclear Medicines doctor before using MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR
- If you are pregnant or believe you may be pregnant
- If you are breastfeeding
- If you are under 18 years old
- If you suffer from any renal function disorder. The specialist may ask you to drink plenty of fluids and to empty your bladder regularly during the first six hours after administration to minimise radiation exposure.

Tc-99m sodium pertechnetate passes from mother to fetus during pregnancy as free pertechnetate form (not binded to the kit). For this reason, if there is any suspicion of pregnancy, please have a pregnancy test before taking this medicine.

If you are a women with childbearing potential, all analyses and tests should be conducted within 10 days following menstruation period. Please inform your doctor about this.

Please consult your doctor if any of these warnings applies to you even in a period in the past.

The solution from ^{99}Mo / ^{99m}Tc GENERATOR is milked and administered by trained personnel. The hospital is responsible for handling and disposal of radioactive medicinal products. This product will only be handled and administered by people who are trained and qualified in the safe handling of radioactive material.

Your doctor will inform you if you need to take any other special precautions after use of this product.

Taking MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR with food and drinks
Considering its administration methods, MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR does not have any interaction with food and drink.

Pregnancy
Ask your doctor or pharmacist before taking any medicine.

You must inform your doctor before administration of MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR, if there is a possibility that you might be pregnant, if you have missed your period or if you are breastfeeding, please inform your doctor.

If you are pregnant, your doctor will make a benefits & risks assessment and will administer this medicine to you only if it is absolutely required for you.

Ask your doctor or pharmacist before using this medicine if you are pregnant or might be pregnant.

Breast-feeding
Ask your doctor or pharmacist before taking any medicine.

If you are breast-feeding ask your Nuclear Medicine doctor for advice before taking this medicine.
You should not be breastfeeding if you are using this medicine, as small amounts of radioactivity can pass to the milk. Therefore, your doctor may delay the investigation until breast-feeding is completed or may ask you to stop breast-feeding. If it is not possible to delay the investigation you should:
- Discard the expressed milk
- Stop breast-feeding at least for 12 hours.

Please ask your Nuclear medicine doctor when you can resume breast-feeding.

Before MONTEK administration you should:
- Drink plenty of water before the start of the examination in order to urinate as often as possible during the first hours after the study.
- You should be fasting for 3 to 4 hours before Meckel's diverticulum scintigraphy to keep the small bowel peristalsis low.

Driving and using machines
This medicine has no negative effect on ability to drive or to operate machines.

Important information about some of the ingredients of MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR
If you are not hypersensitive to any one of the ingredients in MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR, no negative effect associated with these ingredients is expected.

Sodium pertechnetate (^{99m}Tc) solution obtained from MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR contains sodium (Chloride, hydroxide). However, as it contains less than 23 mg sodium per 1 mL dose, a specific warning is not needed to be given for sodium.

Using other medicines
Please tell your Nuclear medicine doctor who will supervise the procedure if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, since they may interfere with the interpretation of images:
- medicine such as atropine or isoprenaline (for heart disease)
- painkillers
- thyroid hormones (to treat thyroid hormone deficiency)
- thiocyanate (antithyroid agent)
- antacids
- sulfonamides (for infections)
- substances containing tin-II ions
- laxatives
- iodine based contrast media
- barium sulphate
- methotrexate (for cancer and other maligne diseases)
- perchlorate (antithyroid agent)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. How MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR will be used?

RADIOPHARMACEUTICALS SHOULD BE ADMINISTERED ONLY BY NUCLEAR MEDICINE PHYSICIANS IN NUCLEAR MEDICINE CENTERS.

There are strict laws on the use, handling and disposal of radiopharmaceutical products. MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR will only be used in special controlled areas. This product will only be handled and given to you by people who are trained and qualified to use it safely. These persons will take special care for the safe use of this product and will keep you informed of their actions.

Instructions for appropriate administration and dose /administration frequency
The Nuclear Medicine doctor supervising the procedure will decide on the quantity to be used in your case. It will be the smallest quantity necessary to get the desired information. The quantity to be administered usually recommended for an adult ranges from 2 to 800 MBq (Mega Becquerel, the united used to express radioactivity).

Use in children and adolescents
In children and adolescents, the quantity to be administered will be adapted to the child's weight.

Method and route of administration
This medicine is used through intravenous injection or by dropping into eyes.

Depending on your disease, your doctor will determine and apply the appropriate dosage of medicine for you

Duration of the procedure
Your Nuclear medicine doctor will inform you about the usual duration of the procedure.

The Nuclear medicine doctor will inform you if you need to take any special precautions after receiving this medicine. Contact your Nuclear medicine doctor if you have any questions.

If you think that the effect of MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR is too high or low, please ask your doctor or pharmacist.

Different age groups

Use in children
Dose to be administered to children will be determined and applied by the treating doctor.

Use in elderly
A specific dosage adjustment is not needed for the elderly patients. It is also determined and applied by the treating doctor.

Special patient populations

Renal /Hepatic impairment
Careful consideration of the activity to be administered to these patients is required since an increased radiation exposure is possible.

If more sodium pertechnetate (^{99m}Tc) is given to you than necessary
An overdose is unlikely because you will only receive a single dose of MONTEK precisely controlled by the Nuclear medicine doctor supervising the procedure. However, in the case of an overdose, you will receive the appropriate treatment.

It is not known what the effect of an overdose is.
The risk of radioactivity damages will increase. Thereupon, your doctor will instruct you to drink plenty of liquids and to urinate frequently in order to accelerate urinary excretion of this medicine from body.

If you forget to use MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR
Do not take double dose in order to equate missed doses.
This incident is not applicable as MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR is applied only for diagnosis purpose directly by a doctor.

If you stop using MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR
MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR is not used for medical treatment purpose.

4. Possible side effects

Like all medicines, MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR can cause side effects for the patients hypersensitive to any of the ingredients.

Your doctor has considered that the clinical benefit that you will obtain form the procedure with the radiopharmaceutical overcomes the risk due to radiation.

This administered radiopharmaceutical will deliver low amount of ionizing radiation with very low risk of cancer and heriditary abnormalities.

Possible side effects are listed below – the frequency is not known as it cannot be estimated from the available data:

- allergic reactions, with symptoms such as
  - skin rash, itching
  - hives
  - swelling at various locations, e.g. of the face
  - shortage of breath
  - redness of the skin
  - coma
- circulatory reactions, with symptoms such as
  - rapid heart beat, slow heart beat
  - fainting
  - blurred vision
  - dizziness
  - headache
  - flushing
- gastrointestinal disorders, with symptoms such as
  - being sick (vomiting)
  - feeling sick (nausea)
  - diarrhoea
- injection site reactions, with symptoms such as
  - skin inflammation
  - pain
  - swelling
  - redness

Reporting side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects, you can help to provide more information on the safety of this medicine.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR?

You will not have to store this medicine. This medicine is stored under the responsibility of the specialist in appropriate premises. Storage of radiopharmaceuticals will be in accordance with national regulation on radioactive materials.

This information is intended for the specialist only.

MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR should be stored in hospitals or administration centers within its original package at room temperature below 25°C.
Expiry time for the generator is 21 days following the manufacturing date and 15 days following the calibration date.

^{99m}Tc sodium pertechnetate solution (Eluate) obtained from the generator should be stored in lead shield below at 25°C and should be consumed within 12 hours.
The expiry time after labeling with the kit should be compared to the labeled product expiry time and the shorter one should be accepted.

Store MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR within its original package, in places away from sight and reach of children.

Use it in compliance with its expiry date.

Do not use MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR after the expiry date which is stated on the packaging.

Marketing authorization holder:
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THE FOLLOWING INFORMATION IS PROVIDED FOR THE MEDICINAL PERSONNEL THAT WILL ADMINISTER THIS MEDICINE

Sodium pertechnetate solution obtained from MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR is radioactive. For this reason, the bottle containing this solution should be kept and stored in an appropriate lead shield.

Patient dose preparation and administration steps should be applied by aseptic techniques.

Although elution from MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR is possible at any time, the level of ^{99m}Tc from eluate is dependent upon the time between first and last elution.

Appropriate shielding should be available to avoid unnecessary radiation exposure for patients, employees and other people.

^{99m}Tc sodium pertechnetate eluate obtained from elution should be stored in lead shield and if it is not clear should not be used.

Eluate is used for 12 hours since the elution date and time in room temperature below 25°C.

As the generator, used vacuum bottles and other post-use wastes and residues are radioactive, they should be disposed of in accordance with the relevant national and international regulations.

Method of preparation

Radiopharmaceuticals should be prepared by the user in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken complying with the requirements of Good Pharmaceutical Manufacturing Practice for radiopharmaceuticals.

Instructions for Use (Elution) of MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR:

Safe handling

Consideration should be given to the safe lifting and carrying of the generators. Local manual handling operations regulations should be observed in order to reduce the risk of injury caused by manual handling activities.

Elution instructions

The facilities used for elutions should comply with the appropriate regulations for safe radiological handling. Strict aseptic techniques should be used during the elution of the generator to ensure sterility of the generator eluate.

To avoid unsatisfactory performance it is important to adhere to the following sequence of elution steps.

First elution

Please perform the elution procedure as described below to obtain sterile, isotonic ^{99m}Tc pertechnetate solution from generator. The generator elution process is illustrated in Figure 1 as a guide for the elution processes.

1. MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR and vials containing NaCl 0.9 % and evacuated vials are prepared in aseptic conditions and therefore solution obtained from elution will be sterile and isotonic.
2. For your own safety and product safety obey aseptic working rules during elution process.
3. Put on mask and sterile disposable gloves before starting the process.
4. Remove the generator and accompanying accessories from their packaging. Place the generator on a flat, level surface, in a suitably authorised and shielded location. **Do not remove** needle protector vials until you are ready to carry out the first elution.
5. Select a sodium chloride 9 mg/ml (0.9%) solution for injection vial containing the required volume of sodium chloride 9 mg/ml (0.9%) solution for injection.
6. Remove the flip-top from the sodium chloride 9 mg/ml (0.9%) solution for injection vial and swab the sodium chloride 9 mg/ml (0.9%) solution for injection vial closure using a supplied swab containing 70% isopropyl alcohol and allow drying.
7. Remove the cover of generator and remove the vials that protect the needle (Figure 1, Position A).
8. Place the sodium chloride 9 mg/ml (0.9%) solution for injection vial onto this needle (Figure 1, Location A), ensuring that it is fully pushed to the bottom of the inlet well.
9. Select an evacuated elution vial and swab the elution vial closure using a supplied swab containing 70% isopropyl alcohol and allow drying. Prior to placing the elution vial inside the elution vial shield ensures that the vial contact surfaces of the shield have been swabbed using the swab containing 70% isopropyl alcohol provided and allow drying. Then, place elution vial inside the elution vial shield.
10. Place the prepared shield containing elution vial on the needle (Figure 1, Location B). Please be sure that the needle hole of the elution vial shield fit the plunger. The plunger is an irremovable spring system. It is used for protection purposes for the needle. Otherwise needle may be damaged or broken. Push down to ensure that elution vial shield is locked with the plunger and the vial is fully located on the elution needle.
11. Elution from generator starts when elution vial shield is pushed to the bottom of the inlet and pertechnetate solution collected in evacuated vial. Air bubbles might form in sodium chloride 9 mg/ml (0.9%) solution for injection vial and solution level will decrease in this vial.
12. Allow at least 3 minutes for the elution to proceed to completion. **Do not remove either the sodium chloride 9 mg/ml (0.9%) solution for injection vial or elution vial before the elution is complete.**
13. After completion of elution, pull elution vial shield vertically. A resistance may be felt before elution vial shield is detached from the plunger, keep pulling the elution vial shield vertically to overcome the resistance and remove it from the plunger. Put the label containing the elution activity, solution volume and elution time on the lead shield.
14. Leave the empty sodium chloride 9 mg/ml (0.9%) solution for injection vial in place until the next elution to preserve sterility.

Subsequent elution

Using a new sanitized sodium chloride 9 mg/ml (0.9%) solution for injection vial of the required volume and an elution vial repeat steps 1-14.

^{99m}Tc sodium pertechnetate is taken from generator at appropriate quantity according to the process and administered to patients through intravenous injection or dropping on eye and scintigraphy is performed.

Patient dosage is calculated using the factors given Table 1 and Table 2 and radioactivity value is measured before application on patient.

As in all preparations to be applied parentally, check the ^{99m}Tc sodium pertechnetate solution physically before application to patient. Do not apply discolored or particle containing solution to patient.

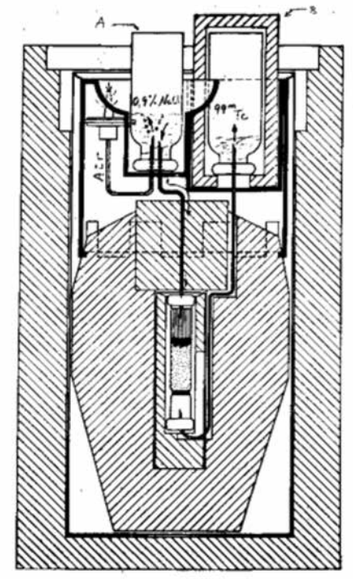

Figure 1 - MON.TEK ^{99}Mo / ^{99m}Tc GENERATOR elution diagram

Table 1: Factors allowing for growth of ^{99m}Tc at various times following the previous elution (^{99m}Tc half-life 6.02 hours)

Hour	Factor	Hour	Factor	Hour	Factor	Hour	Factor	Hour	Factor	Hour	Factor
1	0.094	9	0.579	17	0.788	25	0.879	33	0.918	41	0.935
2	0.179	10	0.615	18	0.804	26	0.884	34	0.921	42	0.937
3	0.256	11	0.648	19	0.818	27	0.892	35	0.924	43	0.938
4	0.324	12	0.678	20	0.831	28	0.898	36	0.926	44	0.940
5	0.386	13	0.705	21	0.843	29	0.903	37	0.929	45	0.941
6	0.442	14	0.729	22	0.853	30	0.907	38	0.930	46	0.941
7	0.492	15	0.751	23	0.863	31	0.911	39	0.932	47	0.941
8	0.538	16	0.771	24	0.871	32	0.915	40	0.934	48	0.942

Table 2: TABLE of ^{99m}Tc ACTIVITIES OBTAINED FROM MON-TEK ^{99}Mo/^{99m}Tc GENERATORS

DAYS		MON.TEK 5		MON.TEK 10		MON.TEK 15		MON.TEK 20		MON.TEK 25		MON.TEK 30		MON.TEK 35		MON.TEK 40		MON.TEK 45		MON.TEK 50	
		mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq	mCi	MBq
-6	Friday	543	20.091	1.079	39.923	1.631	60.347	2.183	80.771	2.734	101.158	3.286	121.582	3.838	142.006	4.390	162.430	4.950	183.150	5.521	204.277
-5	Saturday	418	15.466	831	30.747	1.256	46.472	1.680	62.160	2.105	77.885	2.530	93.610	2.955	109.335	3.380	125.060	3.812	141.026	4251	157.287
-4	Sunday	322	11.914	640	23.680	967	35.779	1.294	47.878	1.621	59.977	1.948	72.076	2.275	84.175	2.602	96.274	2.935	108.590	3273	121.101
-3	Monday	248	9.176	492	18.204	744	27.528	996	36.852	1.248	46.176	1.500	55.500	1.752	64.824	2.004	74.148	2.260	83.614	2520	93.240
-2	Tuesday	191	7.067	379	14.023	573	21.201	767	28.379	961	35.557	1.155	42.735	1.349	49.913	1.543	57.091	1.740	64.383	1940	71.780
-1	Wednesday	147	5.439	292	10.804	441	16.317	590	21.830	740	27.380	889	32.893	1.038	38.406	1.188	43.956	1.340	49.575	1494	55.278
0	**Thursday**	**113**	**4.181**	**225**	**8.325**	**340**	**12.580**	**455**	**16.835**	**570**	**21.090**	**685**	**25.345**	**800**	**29.600**	**915**	**33.855**	**1.032**	**38.173**	**1150**	**42.550**
+1	Friday	87	3.219	173	6.401	261	9.657	350	12.950	438	16.206	527	19.499	616	22.792	704	26.048	794	29.393	886	32.782
+2	Saturday	67	2.479	133	4.921	201	7.437	269	9.953	337	12.469	406	15.022	474	17.538	542	20.054	612	22.633	682	25.234
+3	Sunday	52	1.924	102	3.774	155	5.735	207	7.659	260	9.620	312	11.544	365	13.505	417	15.429	471	17.427	525	19.425
+4	Monday	40	1.480	79	2.923	119	4.403	159	5.883	200	7.400	240	8.880	281	10.397	321	11.877	363	13.419	404	14.948
+5	Tuesday	31	1.147	60	2.220	92	3.404	123	4.551	154	5.698	185	6.845	216	7.992	247	9.139	279	10.332	311	11.507
+6	Wednesday	24	888	46	1.702	70	2.590	94	3.478	118	4.366	142	5.254	166	6.142	190	7.030	215	7.956	240	8.880
+7	Thursday	18	666	36	1.332	54	1.998	73	2.701	91	3.367	109	4.033	128	4.736	146	5.402	166	6.126	185	6.845
+8	Friday	14	518	27	999	42	1.554	56	2.072	70	2.590	84	3.108	98	3.626	113	4.181	127	4.717	142	5.254
+9	Saturday	11	407	21	777	32	1.184	43	1.591	54	1.998	65	2.405	76	2.812	87	3.219	98	3.632	109	4.033
+10	Sunday	8	296	16	592	24	888	33	1.221	41	1.517	50	1.850	58	2.146	67	2.479	76	2.797	84	3.108
+11	Monday	6	222	12	444	19	703	25	925	32	1.184	38	1.406	45	1.665	51	1.887	58	2.154	65	2.405
+12	Tuesday	5	185	9	333	14	518	19	703	24	888	29	1.073	34	1.258	39	1.443	45	1.658	50	1.850
+13	Wednesday	4	148	7	259	11	407	15	555	19	703	22	814	26	962	30	1.110	35	1.277	38	1.406
+14	Thursday	3	111	5	185	8	296	11	407	14	518	17	629	20	740	23	851	27	983	29	1.073
+15	Friday	2	74	4	148	6	222	9	333	11	407	13	481	15	555	18	666	20	757	22	814

*Elution Activity is the activity obtained from a generator eluted at 8 A.M by at least 5 ml sodium chloride 9 mg/ml (0.9%) solution for injection that is not eluted during 24 hours.

** The activities to be obtained are the 90-110% of the given activity amounts.