ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

NeoSpect 47 micrograms, kit for radiopharmaceutical preparation.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 47 micrograms depreotide as depreotide trifluoroacetate.
For a full list of excipients, see section 6.1

To be reconstituted with sodium pertechnetate (^{99m}Tc) solution for injection (not included in this kit).

3. PHARMACEUTICAL FORM

Kit for radiopharmaceutical preparation. White powder for solution for injection.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.
For scintigraphic imaging of suspected malignant tumours in the lung after initial detection, in combination with CT scan or chest X-ray, in patients with solitary pulmonary nodules.

4.2 Posology and method of administration

The medicinal product is for hospital use or in designated Nuclear Medicine Facilities only, by persons experienced in radioisotope diagnostic imaging.

Instructions for reconstitution, handling and disposal are given in section 12.
After reconstitution with sodium pertechnetate (^{99m}Tc) solution for injection, ^{99m}Tc-depreotide is formed.

^{99m}Tc-depreotide is administered intravenously in a single dose. The solution may be diluted with sodium chloride 0.9% w/v solution for injection for more convenient injection. SPECT images (Single Photon Emission Computed Tomography) obtained between 2 and 4 hours following ^{99m}Tc-depreotide injection are required for optimal image interpretation.

Dosage for adults
The recommended dosage is approximately 47 micrograms depreotide (one vial) labelled with 555-740 MBq of technetium-99m.

Dosage for elderly (>65 years)
Experience from clinical trials indicates that no dose adjustment is required.

Children
^{99m}Tc-depreotide is not recommended for use in patients below the age of 18 as data are not available for this age group.

Renal impairment
No dose adjustment is required. See section 4.4

Re-administration
^{99m}Tc-depreotide is indicated for single use only. Repeat administration must be avoided.

4.3 Contraindications

History of hypersensitivity reaction to depreotide, any of the excipients of NeoSpect or sodium pertechnetate (^{99m}Tc) solution for injection. Pregnancy and lactation.

4.4 Special warnings and precautions for use

The contents of NeoSpect are intended only for use in the preparation of ^{99m}Tc-depreotide solution for injection (see section 12). Unlabelled NeoSpect should not be administered directly to the patient.

As with all injectable medicinal products, anaphylactic or anaphylactoid reactions may occur after administration. Familiarity with the practice and technique of resuscitation and treatment of anaphylaxis is essential. Appropriate treatment and equipment should be readily available.

Care should be exercised in patients with impaired renal function, due to lower renal excretion and probable increase in exposure to radioactivity.

Care should be exercised in patients with reduced liver function.

This radiopharmaceutical may be handled only by authorised persons in designated clinical settings. Its receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licenses of the local competent official organisations.

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 Manufacturing Practice (GMP) for pharmaceuticals.

^{99m}Tc-depreotide, must be handled with care, and appropriate safety measures should be used to minimise radiation exposure to clinical personnel. Care should also be taken to minimise radiation exposure to the patient, consistent with proper patient management.

To minimise the dose of radiation absorbed by the bladder, adequate hydration should be encouraged to permit frequent voiding during the first few hours after injection.

Therapy with octreotide acetate can produce severe hypoglycaemia in patients with insulinomas, and other somatostatin analogues are known to impair glucose tolerance. Since depreotide also binds to somatostatin receptors, caution should be exercised when administering this medicinal product to patients with insulinomas or diabetes mellitus.

NeoSpect is not recommended for use in children under 18 years of age because data are not available for this age group.

Re-administration: Clinical data reflecting safety and efficacy of multiple injections are only available in 13 patients. Repeat administration must be avoided.

4.5 Interaction with other medicinal products and other forms of interaction

No specific interaction studies with other medicinal products have been performed, and there are little available data on such interactions.

4.6 Pregnancy and lactation

Pregnancy

Radionuclide procedures carried out on pregnant women also involve radiation doses to the foetus. ^{99m}Tc-depreotide is therefore contraindicated in pregnancy. (See section 4.3)

When it is necessary to administer radioactive medicinal products to women of childbearing potential,

information should always be sought about pregnancy. Any woman who has missed a period should be assumed to be pregnant until proven otherwise. Alternative techniques, which do not involve ionising radiation, should be considered.

Lactation
It is not known whether ^{99m}Tc-depreotide is excreted in human milk, ^{99m}Tc-depreotide is therefore contraindicated during lactation.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Most of the adverse reactions reported were transient and of mild intensity. All were uncommon (0.1%-1%) in occurrence. Most frequently reported were headache, nausea, vomiting, diarrhoea, abdominal pain, dizziness, flushing and fatigue.

For each patient, exposure to ionising radiation must be justifiable on the basis of the likely benefit. The activity administered must be such that the resulting radiation dose is as low as reasonably achievable bearing in mind the need to obtain the intended diagnostic result.
Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. For diagnostic nuclear medicine investigations, the current evidence suggests that these adverse events will occur with low frequency because of the low radiation doses incurred.
For most diagnostic investigations using nuclear medicine procedures, the radiation dose delivered (effective dose equivalent) is less than 20 mSv. Higher doses might be justified in some clinical circumstances.

Observed changes in the laboratory parameters are: increased WBC count, basophils, eosinophils, monocytes and neutrophils, AST, ALT, LDH, total bilirubin and total protein; lowered RBC count and total protein.

4.9 Overdose

No case of overdose has been reported.
Treatment of an overdose should be directed towards the support of vital functions.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Diagnostic radiopharmaceutical for use in tumour detection
ATC code: V09I A05

Technetium (^{99m}Tc) depreotide solution for injection is a diagnostic radiopharmaceutical based upon a synthetic peptide that binds to somatostatin receptors. *In vitro* data and studies in laboratory animals indicate that ^{99m}Tc-depreotide binds with high affinity to somatostatin receptor (SSTR) subtypes 2, 3 and 5. These receptors are hyper-expressed by malignant tumours.

The binding affinity of ^{99m}Tc-depreotide to SSTR was shown in studies of pancreatic tumours in Lewis rats and *in vitro* in human tumour membranes. The data indicate that the ^{99m}Tc-depreotide displays high-affinity binding to somatostatin receptors. The peptide itself has a lower affinity for these receptors. In a clinical study examining the pharmacodynamic effects of the recommended dose of the peptide in human volunteers during an oral GTT (Glucose Tolerance Test), no effects were observed other than the normal physiologic response to oral glucose challenge.

In the pivotal studies, the negative predictive value for NeoSpect in association with CT for solitary pulmonary nodules (SPNs) was 90–96% at a disease prevalence of 30-50%. In the same prevalence range the positive predictive value was in the range 52-72%. The corresponding negative predictive value and positive predictive value for NeoSpect in association with chest X-ray were 96-98% and 61-78% respectively.

In a recent clinical study with a prevalence of malignancy of 49%, the positive predictive value for NeoSpect in association with CT/chest X-ray was 84% (CI 63.1-94.7%) for all SPNs and 81.8% for lesions equal to or less than 3cm. The negative predictive value was 87.5% (CI 66.5-96.7%) for all lesions and 87.5% for lesions equal to or less than 3cm. However, histology was predominantly obtained by fine needle aspiration (FNA) with 5 out of 49 patients having open thoracotomies. In view of the false negative rate of FNA (5-8% false negative rate reported), thoracotomy is considered to be the gold standard. Patients with a negative FNA should be followed up clinically as some FNA biopsies may give false negative results.

The radiation dose from ^{18}FDG-PET (Fluorodeoxyglucose – Positron Emission Tomography) is lower than that from NeoSpect, whilst still achieving high sensitivity and specificity. However PET is not widely available throughout Europe.

5.2 Pharmacokinetic properties

Studies in healthy volunteers have demonstrated that the tracer confers three-compartment pharmacokinetic characteristics with a distribution half-life of less than 5 minutes and a terminal half-life of about 20 hours, and a steady-state volume of distribution of 1.5 to 3 l/kg. Total clearance averaged 2 to 4 ml/min/kg. Renal clearance averaged about 0.3 ml/min/kg. External whole-body gamma scintigraphy showed highest location of radioactivity in the abdomen. One to 18% of the injected dose of radioactivity appeared in the urine at 4 hours after injection.

Plasma radioactivity is predominantly (>90%) in parent form, i.e. as ^{99m}Tc-depreotide. The majority of the radioactivity excreted in urine is in parent form.

^{99m}Tc-depreotide binds to the extent of about 12% to plasma proteins in patients and healthy volunteers.

5.3 Preclinical safety data

^{99m}Tc-depreotide was not mutagenic *in vitro* in the Ames test or mouse lymphoma test, and it was not clastogenic *in vivo* in the mouse micronucleus test. Toxic effects observed in the animal studies were not considered to be relevant in clinical use in humans. Studies have not been conducted to evaluate carcinogenic potential or effects on fertility.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stannous chloride dihydrate 50 micrograms (essential excipient)
Sodium α-D-glucoheptonate dihydrate
Disodium edetate
Hydrochloric acid and/or sodium hydroxide (pH adjustment)

6.2 Incompatibilities

In the absence of incompatibility studies, ^{99m}Tc-depreotide must not be mixed with other medicinal products. A separate cannula should be used.

6.3 Shelf life

18 months.

Following reconstitution and radiolabelling, the material must be used within 5 hours as radiochemical purity and stability have been demonstrated for 5 hours at 25°C.

6.4 Special precautions for storage

Store in a freezer at or below -10 °C.
Store the reconstituted solution for injection for no more than 5 hours at 15 °C - 25 °C using appropriate radiation shielding.
Storage of radiopharmaceuticals should be in accordance with national regulations on radioactive materials.

6.5 Nature and content of container

The product is filled in 5 ml type I glass vials. The containers are closed with butyl rubber stoppers and sealed with aluminium caps. NeoSpect is supplied in packs of 1 vial and 5 vials, each vial containing 47 micrograms depreotide. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

See section 12

7. MARKETING AUTHORISATION HOLDER

CIS bio international
B.P. 32
91192 GIF sur YVETTE cedex
FRANCE

8. MARKETING AUTHORISATION NUMBERS

EU/1/00/154/001
EU/1/00/154/002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29.11.2000 / 31.01.2006

10. DATE OF REVISION OF THE TEXT

11. DOSIMETRY

Technetium-99m disintegrates by isomeric transition with the emission of gamma radiation with an energy of 140 keV and a half life of 6 hours to technetium-99, which can be regarded as quasi stable.

For this product, the effective dose resulting from an administered activity of 555-740 MBq is typically 8.88–11.84 mSv for a 70 kg individual.

Based on human data, the absorbed radiation doses by individual organs of an average human adult (70 kg) from an intravenous injection of the agent are listed below. The values are listed in descending order as mGy/MBq and assume urinary bladder emptying at 4.8 hours.

Estimated absorbed radiation dose

Target Organ	mGy/MBq
Kidneys	0.090
Spleen	0.042
Testes	0.031
Thyroid gland	0.024
Bone marrow	0.021
Liver	0.021
Bone surface	0.015
Heart wall	0.014
Lungs	0.014
Adrenal glands	0.012
Pancreas	0.010
Urinary bladder	0.0089
Uterus	0.0084
Small intestine	0.0050
Upper large intestine	0.0050
Ovaries	0.0042
Lower large intestine	0.0038

Dose calculations were performed using the standard MIRD method (MIRD Pamphlet No. 1 rev., Soc. Nucl. Med., 1976). The effective dose (ED) calculated in accordance with ICRP Publication 60 (Pergamon Press, 1991) gave a value of 0.016 mSv/MBq, corresponding to 11.84 mSv after administration of 740 MBq.

Due to the short, six-hour half-life of technetium-99m, less than 0.1% of the radioactivity remains 60 hours after administration.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

After use, the container and any unused material must be disposed of as radioactive waste in accordance with local requirements.

NeoSpect is used for preparation of technetium (^{99m}Tc) depreotide solution for injection. Sodium pertechnetate (^{99m}Tc) solution for injection (Ph.Eur) is used for reconstitution.

Instructions for the preparation of ^{99m}Tc-depreotide:

The administration of radiopharmaceutical creates risks for other persons from external radiation or contamination from spills of urine, vomiting etc. Local regulations for radioactive materials must be applied in the radiation protection precautions and waste disposal.

Use aseptic technique throughout. The user should wear waterproof gloves and use shielding at all times when handling the reconstituted vial or syringes containing the radioactive agent.

The activity of ^{99m}Tc-depreotide administered to the patient should be measured using a suitably calibrated dose calibrator immediately prior to administration to the patient.

1. Prepare a boiling water bath containing a lead vial shield standing in and equilibrated with the boiling water bath.
2. Allow the vial kit to warm to 15 °C - 30 °C and place it in a suitable shielding container and sanitise the rubber septum with sanitising alcohol swab.
3. Using a shielded syringe, inject the required radioactivity of up to 1.8 GBq of sodium pertechnetate (^{99m}Tc) solution for injection, (diluted as appropriate with sodium chloride 0.9% w/v solution for injection to a total of 1 ml) into the shielded vial. See Cautionary notes 1 and 2

below.
Before removing the syringe from the vial, withdraw a volume of gas from above the solution equal to the volume of pertechnetate added in order to normalise the pressure inside the vial. Swirl gently for 10 seconds in order to ensure complete dissolution of the powder.

4. Immediately transfer the reaction vial to a lead safe in the boiling water bath, maintaining the vial in the upright position. Incubate for 10 minutes in this condition. Allow the vial to cool to body temperature (about 15 minutes) at room temperature before proceeding. The vial should not be cooled under running water, as this may impede labelling.
5. Assay the total radioactivity, complete the user radiation label and attach it to the lead shielded vial.
6. Parenteral medicinal products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit: visually inspect the reconstituted solution at a safe distance through leaded glass. Do not use if the solution is not clear or if it contains visible particulate matter.
7. Store the reconstituted solution for injection upright at 15 °C – 25 °C and use within 5 hours of preparation.

Cautionary notes

1. The volume of diluted sodium pertechnetate (^{99m}Tc) solution for injection, added to the vial must be 1 ml.
2. The radioactive amount of the diluted generator eluate must not exceed 1.8 GBq when it is added to the vial. The amount of radioactivity is calculated according to the planned time of injection to the patient, to obtain a single patient dose of 555 – 740 MBq from the entire reconstituted vial.
3. Safety and effectiveness of ^{99m}Tc-depreotide were established using investigational material shown to have a radiochemical purity of at least 90% by ITLC prior to administration to patients in clinical studies.
4. The contents of the NeoSpect vial are not radioactive; however, after the addition of sodium pertechnetate (^{99m}Tc) solution for injection, adequate shielding of the final preparation must be maintained.
5. The labelling reaction involved in the preparation of ^{99m}Tc-depreotide depends upon maintaining tin in the divalent (reduced) state. Any oxidant present in the sodium pertechnetate (^{99m}Tc) solution for injection might adversely affect the quality of the preparation. Sodium pertechnetate (^{99m}Tc) solution for injection containing oxidants ought not to be used for the preparation of the labelled product.
6. Sodium chloride 0.9% w/v solution for injection must be used as the diluent. Do not use bacteriostatic sodium chloride solution for injection as a diluent for pertechnetate, because it might adversely affect the radiochemical purity and, hence, the biological distribution of the tracer.
7. The contents of the NeoSpect vial are sterile. The vial contains no bacteriostatic preservative. It is essential that the user follows the directions carefully and adheres to aseptic procedures during the preparation of the radiopharmaceutical.

Quality control

An assay of the radiochemical purity of the prepared injection can be performed using the following chromatographic procedures.

Equipment and Materials

1. Two Gelman ITLC-SG strips (2 cm x 10 cm)
2. Two developing tanks and covers
3. Saturated sodium chloride solution (SSCS)[1] ([1] See section 1.) below)
4. 1:1 (v/v) methanol / 1M ammonium acetate (MAM)[2] ([2] See section 2.) below)
5. One 1 ml syringe and 21-gauge needle
6. Suitable counting equipment

1) Saturated sodium chloride solution (SSCS)
May be prepared by adding about five grams of sodium chloride to the bottom of one chromatography chamber; add approximately 10 millilitres of distilled water to the solid sodium chloride and shake periodically during 10 to 15 minutes. Solid sodium chloride should remain at the bottom of the jar; if there is no residue, add more solid sodium chloride and shake again for 10 to 15 minutes. Continue until a solid residue remains. (The saturated sodium chloride solution can be reused. Add more distilled water or sodium chloride as needed for subsequent use always maintaining some undissolved sodium chloride at the bottom of the chamber.)

2) 1:1 Methanol / 1M Ammonium Acetate (MAM)
1M Ammonium Acetate - Add 3.9 ± 0.1 grams of solid ammonium acetate to a 50 ml volumetric flask. Add approximately 15 ml of distilled water to the flask, stopper, and swirl to dissolve the solid. Add distilled water up to the 50 ml mark, mix thoroughly. The ammonium acetate solution can be used for up to one month. Label the solution with a one month expiration date.
1:1 Methanol / 1M Ammonium Acetate (MAM) - Carefully mix one part methanol with one part 1M Ammonium Acetate. The MAM should be prepared fresh daily.

METHOD

1. Pour the MAM and SSCS into separate developing tanks to a depth of approximately 0.5 cm. Cover the tanks and allow to equilibrate with the solvent vapours.
2. Mark two Gelman ITLC-SG strips with a light pencil at 1 cm from the bottoms of each.
3. Spot one drop (approximately 5-10 microlitres) of ^{99m}Tc-depreotide at the origin of each strip using the hypodermic needle. Do not allow the spots to dry.
CAUTION: Do not allow the needle to touch the strip.
4. Place the developing tanks behind a lead shield.
5. Place one ITLC-SG strip in the MAM developing solvent. Place the second ITLC-SG strip in the SSCS developing solvent. Place the strips upright in the respective developing solvent such that the spot is above the solvent line and the top of each strip leans against the side of the tank.
CAUTION: Do not allow the sides of the strip to contact the side of the tank. Cap the developing tanks.
6. Allow the solvent front to move to the top of the strip.
7. Remove the strip from the tank and allow the strip to dry behind a lead shield.
8. Cut the strips as described below:
ITLC-SG MAM: cut the strip at Rf 0.40 (40% of the distance from the origin to the solvent front).
ITLC-SG SSCS: cut the strip at Rf 0.75 (75% of the distance from the origin to the solvent front)
9. Count each strip section in a dose calibrator and interpret the results as follows:

Percent technetium-99m non-mobile material = A

$$A = 100 \times \frac{\text{Radioactivity in bottom piece of ITLC-SG MAM strip (Rf 0-0.40)}}{\text{Total radioactivity in both pieces of ITLC-SG MAM strip}}$$

Percent technetium (99mTc) pertechnetate, technetium-99m labelled glucoheptonate and technetium-99m labelled edetate = B

$$B = 100 \times \frac{\text{Radioactivity in top piece of ITLC-SG SSCS strip (Rf 0.75-1.0)}}{\text{Total radioactivity in both pieces of ITLC-SG SSCS Strip}}$$

10. Percent ^{99m}Tc-depreotide: 100 - (A + B). A value of at least 90% should be obtained in a satisfactory preparation.

Detailed information on this product is available on the website of the European Medicines Agency (EMEA) http://www.emea.europa.eu/

ANNEX II

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OF THE MARKETING AUTHORISATION

A. MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release
CIS bio international
B.P. 32
91192 GIF sur YVETTE cedex
FRANCE

B. CONDITIONS OF THE MARKETING AUTHORISATION

- **CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER**

Medicinal product subject to restricted medical prescription (See Annex I: Summary of Product Characteristics, section 4.2)

- **CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT**

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

1. NAME OF THE MEDICINAL PRODUCT

NeoSpect 47 micrograms, kit for radiopharmaceutical preparation

Depreotide

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each vial contains: 47 micrograms depreotide as depreotide trifluoroacetate

3. LIST OF EXCIPIENTS

Sodium α-D-glucoheptonate dihydrate, stannous chloride dihydrate, disodium edetate, hydrochloric acid and/or sodium hydroxide q.s.

4. PHARMACEUTICAL FORM AND CONTENTS

1 vial
5 vials

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Diagnostic agent for scintigraphic imaging.
Reconstitute with sodium pertechnetate (^{99m}Tc) injection.
Intravenous use.
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

Store in a freezer at or below –10 °C.
After reconstitution, store at 15 °C – 25 °C and use within 5 hours.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

After use, dispose of as radioactive waste.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CIS bio international
B.P. 32
91192 GIF sur YVETTE cedex
FRANCE

12. MARKETING AUTHORISATION NUMBERS

EU/1/00/154/001 1 vial
EU/1/00/154/002 5 vials

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

NeoSpect 47 micrograms, kit for radiopharmaceutical preparation
Depreotide
Intravenous use

2. METHOD OF ADMINISTRATION

Reconstitute with sodium pertechnetate (^{99m}Tc) injection

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

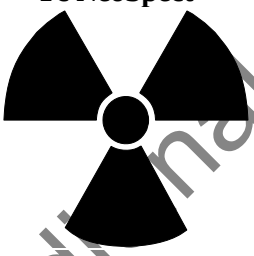
Batch:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

6. OTHER

Sticker label to be applied after reconstitution:

^{99m}Tc NeoSpect



MBq
ml
hour/date
^{99m}Tc

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

NeoSpect 47 micrograms. Kit for radiopharmaceutical preparation
Depreotide

Please read this leaflet carefully. It tells you about your medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. WHAT NeoSpect IS AND WHAT IT IS USED FOR

Product type
NeoSpect is a radiopharmaceutical product used for diagnostic purposes. A diagnostic radiopharmaceutical is a product which, when injected, temporarily collects in a particular part of the body (for example a tumour). Because the substance contains a small amount of radioactivity it can be detected from outside the body using special cameras, and a picture, known as a scan, can be taken. This scan will show exactly the distribution of the radioactivity within the body. This can give the doctor valuable information such as the location of a tumour.

What NeoSpect is used for
NeoSpect is for diagnostic use only. NeoSpect is used to provide pictures which show the location of suspected malignant cancer tissue (a tumour) in the lung. When injected, the radiolabelled compound binds to malignant cancer tissue. Your doctor will then take a picture (scan) of your lungs using a special camera. The area where the radioactive compound is collected, will light up on the picture and give information on the location of the tumour. The evaluation also includes examinations by CT-scan or chest X-ray.

2. BEFORE YOU USE NeoSpect

Do not use NeoSpect
- if you are allergic (hypersensitive) to depreotide or any of the other ingredients of NeoSpect or to the radioactive technetium.
- if there is any possibility that you are pregnant.
- if you are breast-feeding.

Take special care with NeoSpect
- if you are suffering from diabetes or other related conditions
- if you have a renal disease
- if you have a liver disease

If any of the above mentioned conditions are applicable to you, you should inform your doctor.

NeoSpect is not recommended for use in children under 18 years of age, as data are not available for this age group.

The use of NeoSpect does involve exposure to small amounts of radioactivity, however your doctor will always consider the possible risks and benefits when considering the use of this product.

To minimise the dose of radiation absorbed by the bladder, the intake of fluids should be increased during the first few hours after injection to permit frequent voiding.

Taking other medicines
There is only limited data available regarding interactions with other products.
Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

Pregnancy and breast-feeding
You should tell your doctor if there is any possibility that you are pregnant, or if you are breast-feeding.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed.
However, it is not considered likely that NeoSpect will affect your ability to drive or to operate machinery.

3. HOW TO USE NeoSpect

Dosage and administration

NeoSpect is for use in patients over the age of 18 years.

The recommended dosage is one vial (approximately 47 micrograms of depreotide) labelled with 555-740 MBq of technetium-99m.

Radiolabelled NeoSpect is administered as a single injection into a vein. After labelling with the radioactive sodium pertechnetate (^{99m}Tc) solution for injection, radiolabelled NeoSpect will be injected before the scan is taken.

The scanning may take place 2-4 hours after injection of NeoSpect.

Any ^{99m}Tc-depreotide which remains in your body, will naturally lose its radioactivity within 2-3 days.

Because there are strict laws covering the use, handling and disposal of radioactivity, NeoSpect will always be used in a hospital or a similar setting. It will only be handled and administered by people who are trained and qualified in the safe handling of radioactive material.

Overdose
If overdose is suspected, symptomatic treatment will be administered. Your doctor may recommend that you drink plenty of fluids to speed removal of traces of the radiopharmaceutical from your body.

4. POSSIBLE SIDE EFFECTS

Like all medicines, NeoSpect can cause side effects, although not everybody gets them.

Most of the side effects reported were transient and of mild intensity.
Most frequently reported were:

*	headache	*	nausea
*	vomiting	*	diarrhoea
*	abdominal pain	*	dizziness
*	flushing	*	fatigue

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

5. HOW TO STORE NeoSpect

Keep out of the reach and sight of children.

The product label includes the appropriate storage conditions and the expiry date for the product.
Do not use NeoSpect after the expiry date which is stated on the label.

Trained hospital staff will ensure the correct storage of NeoSpect.

6. FURTHER INFORMATION

What NeoSpect contains

- The active substance is 47 micrograms depreotide as depreotide trifluoroacetate.
- The other ingredients are sodium glucoheptonate dihydrate, stannous chloride dihydrate, disodium edetate and hydrochloric acid and/or sodium hydroxide to adjust pH.

What NeoSpect looks like and contents of the pack

The product is a kit for radiopharmaceutical preparation.
NeoSpect is a powder for solution for injection that has to be dissolved and labelled with radioactive technetium before use. When a solution of the radioactive substance sodium pertechnetate (^{99m}Tc) is added to the vial, ^{99m}Tc-depreotide is formed. This solution is ready for injection into a vein.

Pack sizes

1 vial containing 47 micrograms of depreotide.
5 vials, each vial containing 47 micrograms of depreotide.
Not all pack sizes may be marketed.

Marketing Authorisation Holder:

CIS bio international
B.P. 32
91192 GIF sur YVETTE cedex
FRANCE

Manufacturer responsible for batch release:

CIS bio international
B.P. 32
91192 GIF sur YVETTE cedex
FRANCE

This leaflet was last approved in