B. PACKAGE LEAFLET FOR RADIOPHARMACEUTICALS

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

{(Invented) name strength pharmaceutical form}
{Active substance(s)}
[The (invented) name of the medicinal product (referred to as X throughout this document) followed by the strength and pharmaceutical form (i.e. as it appears in the SmPC) should be stated here in bold. This should be followed by the active substance(s) (as stated on the label section 1), which may be written on the line below.]

Read all of this leaflet carefully before you will be administered this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your referring doctor or the specialist physician in Nuclear Medicine who will supervise the procedure.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your your referring doctor or the specialist physician in Nuclear Medicine who has supervised the procedure.

In this leaflet:

1. WHAT X IS AND WHAT IT IS USED FOR

<This medicine is a radiopharmaceutical product for diagnostic use only.>
<This medicine is a radiopharmaceutical product for therapy only.>

X is used for <indication understandable to the patient>

2. BEFORE X IS ADMINISTERED

X must never be used
- <if you are allergic (hypersensitive) to {active substance(s)} or any of the other ingredients of X or to any of the components of the labelled radiopharmaceutical.>
- <if...>

Take special care with X
- <if you ...>
- <when ...>
- < Before treatment with X, …>

Inform the specialist in Nuclear Medicine in the following cases :
- if you are pregnant or believe you may be pregnant
- if you are breast-feeding
- if you are under 18 years old

<Taking> <Using> other medicines
Please tell your doctor or the specialist physician in Nuclear Medicine who will supervise the procedure if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Please tell your physician if you are taking, or have been administered, any of the following medicines/substances , since they may interfer with your physician interpretation of the images:
- <product specific>

<Taking> X with food and drink

Pregnancy and breast-feeding
You must inform the specialist physician in Nuclear Medicine before the administration of X if there is a possibility you might be pregnant, if you have missed your period or if you are breast-feeding.
When in doubt, it is important to consult your physician or the specialist physician in Nuclear Medicine who will supervise the procedure.

If you are pregnant <product specific>
Your physician will only consider this examination during your pregnancy in case of absolute necessity.

If you are breast-feeding <product specific>
Resuming breast-feeding should be in agreement with the specialist in Nuclear Medicine. medicine who will perform the investigation.
Please ask your doctor or the specialist physician in Nuclear Medicine who will supervise the procedure before taking any medicines.

Before X administration you should:
- <drink plenty of water and to be well hydrated before the start of the examination in order to urinate as often as possible during the first hours after the study. >
- <avoid any major physical activity>
- <be fasting for at least 4 hours>
- …

After administration of X has been performed, you should:
- <avoid any close contact with young children for the 12 hours following the injection>
- <urinate frequently in order to eliminate the product from your body>
- …

There are strict laws on the use, handling and disposal of radiopharmaceutical products. {(Invented) name} will only be used in a hospital. 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.

Driving and using machines
<It is considered unlikely that X will affect your ability to drive or to operate machinery or <product specific>
<Do not drive <because...>.>
<Do not use any tools or machines.>

Important information about some of the ingredients of X

Use in children

3. HOW WILL X BE USED?

The specialist physician in Nuclear Medicine supervising the procedure will decide on the quantity of X to be used in your case. It will be the minimal quantity necessary to get <the desired information> <the desired effect>.
The quantity to be administered usually recommended for an adult ranges from <product specific> to <product specific> MBq.

<Use in children>
In case of paediatric population , the quantity to be administered will be adapted to the child's body mass.

Administration of X and conduct of the procedure

Duration of the procedure
Your physician will inform you about the usual duration of the procedure.

If you have been administered more X than you should
An overdose is almost impossible
< because you will only receive a single dose of X precisely controlled by the specialist physician supervising the procedure.> However, in the case of an overdose, you will receive the appropriate treatment. <product specific>
Should you have any further question on the use of X, please ask your doctor or the specialist physician in Nuclear Medicine who supervises the procedure.

4. POSSIBLE SIDE EFFECTS

<for diagnostic radiopharmaceuticals only>
Like all medicines, X can cause side effects, although not everybody gets them.
<they are exceptional>
This administered radiopharmaceutical will deliver <low> amount of ionising radiation with very low risk of cancer and hereditary abnormalities.

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

If you notice any side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or the specialist physician in Nuclear Medicine who supervises the procedure.

<for therapeutic radiopharmaceuticals>
Your doctor has considered that the clinical benefit that you will obtain from the procedure with the radiopharmaceutical overcomes the risk due to radiation.
If you notice any of the side effects, or if you notice any side effects not listed in this leaflet, please tell your doctor or the specialist physician in Nuclear Medicine who supervises the procedure.

5. FURTHER INFORMATION

What X contains
- The active substance(s) is (are)…
- The other ingredient(s) is (are)...

What X looks like and contents of the pack

Marketing Authorisation Holder and Manufacturer

{Name and address}
<{tel}>

<{fax}>
<{e-mail}>

<This medicinal product is authorised in the Member States of the EEA under the following names:>

<For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:>

België/Belgique/Belgien
{Nom/Naam/Name}
<{Adresse/Adres/Anschrift }
B-0000 {Localité/Stad/Stadt}>
Tél/Tel: + {N° de téléphone/Telefoonnummer/ Telefonnummer}
<{e-mail}>

Luxembourg/Luxemburg
{Nom}
<{Adresse}
L-0000 {Localité/Stadt}>
Tél/Tel: + {N° de téléphone/Telefonnummer}
<{e-mail}>

България
{Име}
<{Адрес}
{Град} {Пощенски код}>
Тел.: + {Телефонен номер}
<{e-mail}>

Magyarország
{Név}
<{Cím}
H-0000 {Város}>
Tel.: +Telefonszám}
<{e-mail}>

Česká republika
{Název}
<{Adresa}
CZ {město}>
Tel: +{telefonní číslo}
<{e-mail}>

Malta
{Isem}
<{Indirizz}
MT-0000 {Belt/Raħal}>
Tel: + {Numru tat-telefon}
<{e-mail}>

Danmark
{Navn}
<{Adresse}
DK-0000 {by}>
Tlf: + {Telefonnummer}
<{e-mail}>

Nederland
{Naam}
<{Adres}
NL-0000 XX {stad}>
Tel: + {Telefoonnummer}
<{e-mail}>

Deutschland
{Name}
<{Anschrift}
D-00000 {Stadt}>
Tel: + {Telefonnummer}
<{e-mail}>

Norge
{Navn}
<{Adresse}
N-0000 {poststed}>
Tlf: + {Telefonnummer}
<{e-mail}>

Eesti
(Nimi)
<(Aadress)
EE - (Postiindeks) (Linn)>
Tel: +(Telefoninumber)
<{e-mail}>

Österreich
{Name}
<{Anschrift}
A-00000 {Stadt}>
Tel: + {Telefonnummer}
<{e-mail}>

Ελλάδα
{Όνομα}
<{Διεύθυνση}

Polska
{Nazwa/ Nazwisko:}
<{Adres:}

GR-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{e-mail}>

España
{Nombre}
<{Dirección}
E-00000 {Ciudad}>
Tel: + {Teléfono}
<{e-mail}>

France
{Nom}
<{Adresse}
F-00000 {Localité}>
Tél: + {Numéro de téléphone}
<{e-mail}>

Ireland
{Name}
<{Address}
IRL - {Town} {Code for Dublin}>
Tel: + {Telephone number}
<{e-mail}>

Ísland
{Nafn}
<{Heimilisfang}
IS-000 {Borg/Bær}>
Sími: + {Símanúmer}
<{Netfang }>

Italia
{Nome}
<{Indirizzo}
I-00000 {Località}>
Tel: + {Numero di telefono}>
<{e-mail}>

Κύπρος
{Όνομα}
<{Διεύθυνση}
CY-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{e-mail}>

Latvija
{Nosaukums}
<{Adrese}
{Pilsēta}, LV{Pasta indekss }>
Tel: + {Telefona numurs}
<{e-mail}>

Lietuva
{pavadinimas}
<{adresas}
PL – 00 000{Miasto:}>
Tel.: + {Numer telefonu:}
<{e-mail}>

Portugal
{Nome}
<{Morada}
P-0000–000 {Cidade}>
Tel: + {Número de telefone}
<{e-mail}>

România
{Nume}
<{Adresă}
{Oraş} {Cod poştal} – RO>
Tel: + {Număr de telefon}
<{e-mail}>

Slovenija
{Ime}
<{Naslov}
SI-0000 {Mesto}>
Tel: + {telefonska številka}
<{e-mail}>

Slovenská republika
{Meno}
<{Adresa}
SK-000 00 {Mesto}>
Tel: + {Telefónne číslo}
<{e-mail}>

Suomi/Finland
{Nimi/Namn}
<{Osoite/Adress}
FIN-00000 {Postitoimipaikka/Stad}>
Puh/Tel: + {Puhelinnumero/Telefonnummer}
<{e-mail}>

Sverige
{Namn}
<{Adress}
S-000 00 {Stad}>
Tel: + {Telefonnummer}
<{e-mail}>

United Kingdom
{Name}
<{Address}
{Town} {Postal code} – UK>
Tel: + {Telephone number}
<{e-mail}>

LT {pašto indeksas} {miestas}>
Tel: +370{telefono numeris}
<{e-mail}>

This leaflet was last approved in {MM/YYYY}

<This medicine has been given “conditional approval”.
This means that there is more evidence to come about this medicine.
The European Medicines Agency will review new information on the medicine every year and this leaflet will be updated as necessary.>

<This medicine has been authorised under “Exceptional Circumstances”.
This means that <because of the rarity of this disease> <for scientific reasons> <for ethical reasons> it has been impossible to get complete information on this medicine.
The European Medicines Agency will review any new information on the medicine every year and this leaflet will be updated as necessary.>

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu <There are also links to other websites about rare diseases and treatments.>
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<The following information is intended for medical or healthcare professionals only:>
The complete SmPC of {(Invented) name} is provided <as a separate document> <as a tear-off section at the end of the printed leaflet> in the product package, with the objective to provide healthcare professionals with other additional scientific and practical information about the administration and use of this radiopharmaceutical.

Please refer to the SmPc (SmPc should be included in the box)