



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

## Guideline on core SmPC and package leaflet for radiopharmaceuticals

Draft

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This guideline (EMA/CHMP/167834/2011) replaces the core SmPC for Radiopharmaceuticals (CHMP/EWP/430004/10) and the core Package Leaflet for Radiopharmaceuticals (CHMP/EWP/430144/10).

Comments should be provided using using this [template](#). The completed comments form should be sent to [radiopharmaceuticalsDG@ema.europa.eu](mailto:radiopharmaceuticalsDG@ema.europa.eu)

Keywords	<i>Radiopharmaceuticals, radionuclide, kit for radiopharmaceutical preparation, core SmPC, core Package Leaflet</i>
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# Guideline on core SmPC and package leaflet for radiopharmaceuticals

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## **Executive summary**

This guideline describes the information to be included in the Summary of Products Characteristics (SmPC) and Package Leaflet for Radiopharmaceuticals.

### **1. Introduction (background)**

The purpose of this core SmPC and Package Leaflet is to provide applicants and regulators with harmonised guidance on the information to be included in the Summary of product characteristics (SmPC) for Radiopharmaceuticals<sup>1</sup>. This guideline should be read in conjunction with the QRD product information templates and the guideline on Summary of Product Characteristics.

In the SmPC for Radiopharmaceuticals, all units should be expressed as SI unit.

### **2. Scope**

This core SmPC and Package Leaflet covers all radiopharmaceuticals including kits for radiopharmaceutical preparation.

### **3. Legal basis**

This guideline has to be read in conjunction with Article 11 of Directive 2001/83 as amended, and the introduction and general principles (4) and part I of the Annex I to Directive 2001/83 as amended.

### **4. Core SmPC and package leaflet for radiopharmaceuticals**

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<sup>1</sup> Concept paper on the harmonisation and update of the clinical aspects in the authorised conditions of use for radiopharmaceuticals and other diagnostic medicinal products (EMA/CHMP/EWP/12052/2008)

## **CORE SmPC and Package Leaflet FOR RADIOPHARMACEUTICALS**

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}  
[Please insert the strength at the date and time of calibration]

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

*[For radiolabelled radiopharmaceuticals, the physical half-life of the radionuclide should be stated with a summary of the energies of the principal particle and photon emissions.*

*In case of a non-radiolabelled radiopharmaceutical kit, the corresponding information concerning the intended radionuclide should be listed at the beginning of Section 11. In this case should be stated here:]*  
“The radionuclide is not part of the kit”

<Excipient(s):>  
<For a full list of excipients, see section 6.1. >

## 3. PHARMACEUTICAL FORM

*[Product specific]*

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

*[The text should be as short and precise as possible.]*  
*[If indications are diagnostic:]* <This medicinal product is for diagnostic use only. >  
*[For kits for radiopharmaceutical preparation:]* <After radiolabelling with [e.g. sodium pertechnetate (<sup>99m</sup>Tc) solution], [the solution obtained] is indicated in <adults> <children> <aged {x to y}> <years> <months> for ...>

### 4.2 Posology and method of administration

#### Posology

<Adults>

*[Posology should as a general rule*  
- state a suggested activity range  
- be based on a patient of average weight (70 kg).

*The activity range should be stated in MBq in round numbers. A statement that “other activities may be justifiable” may also be considered appropriate.*

*Reference to European procedural guidelines should be made if required.]*

<Elderly population>

Renal impairment / Hepatic impairment

<Careful consideration of the activity to be administered is required since an increased radiation exposure is possible in these patients.>

#### <Paediatric population>

*[Paediatric dosing regimens, when applicable, should be clearly stated when an indication exists in this subgroup. If there are data available which are not sufficient to support an indication in the paediatric population, these data may be summarised in section 5.1 of the SmPC with a cross reference from section 4.2, Paediatric Population. Reference could be made to relevant data proposed by bodies specialised in radiation protection and/or Nuclear Medicine.]*

<The use in children and adolescents has to be considered carefully, based upon clinical needs and assessing the risk/benefit ratio in this patient group. The activities to be administered to children and to adolescents may be calculated according to *[include here relevant data proposed by bodies specialised in radiation protection and/or Nuclear Medicine]*. >

*[When the minimum recommended activity in the EANM dosage card for Paediatrics is different than the baseline activity, it should be stated here.]*

#### Method of administration

*[Product specific, it should be specified here and in the labelling if multidose or for single use only. This information of multidose/single use is also to be included in the labelling.]*

*[For kits for radiopharmaceutical preparation:]* This medicinal product should be reconstituted before administration to the patient.

<For patient preparation, see section 4.4.>

*[For a diagnostic radiopharmaceutical intended for imaging or for a therapeutic radiopharmaceutical allowing imaging biodistribution]*

#### Image acquisition

*[General recommendations should be given about the recommended (minimal) number of imaging times, the delay between administration and imaging, some particular types of acquisition that are recommended in all or some of the indicated clinical settings, such as tomoscintigraphy SPECT, dynamic acquisition (rapid change of biodistribution over time), fusion with another imaging modality ... ]*

### **4.3 Contraindications**

<Hypersensitivity to the active substance(s), to any of the excipients <or {name of the residue(s)}> <or to any of the components of the labelled radiopharmaceutical.>

### **4.4 Special warnings and precautions for use**

#### Potential for hypersensitivity or anaphylactic reactions

*[In case hypersensitivity or anaphylactic reactions with general or life-threatening manifestation have been observed:]* If hypersensitivity or anaphylactic reactions occur, the administration of the medicinal product must be discontinued immediately and intravenous treatment initiated, if necessary. To enable immediate action in emergencies, the necessary medicinal products and equipment such as endotracheal tube and ventilator must be immediately available.

#### Individual benefit/risk justification

*[The as low as reasonably achievable (ALARA) statement should be included in every radiopharmaceutical:]* For each patient, the radiation exposure must be justifiable by the likely benefit.

The activity administered should in every case be as low as reasonably achievable to obtain the required <diagnostic information> <or, therapeutic effect>.

<Renal impairment> <Hepatic impairment>

<Careful consideration of the benefit risk ratio in these patients is required since an increased radiation exposure is possible.>

*[Peculiarities concerning radiopharmaceuticals with biliary excretion or pulmonary excretion may also be stated here.]*

Paediatric population

For information on the use in paediatric population, see sections 4.2. or 5.1..

Careful consideration of the indication is required since the effective dose per MBq is higher than in adults (see section 11)

Patient preparation

<The patient should be well hydrated before the start of the examination and urged to void as often as possible during the first hours after the examination in order to reduce radiation.

*[or, in case of administration of higher activities:]* Patients should be encouraged to increase oral fluids and urged to void as often as possible to reduce bladder radiation, especially after high activities e.g. for radionuclide therapy. Patients with bladder voiding problems should be catheterized after high activity [...] administration.>

<Interpretation of [active substance] images>

Specific warnings

*[This section is not only for excipients, but also for any specific warning to a radiopharmaceutical.]*

<This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium-free’.>

<According to the time of conditioning injection for the patient, the content of sodium may in some cases be greater than 1 mmol. This should be taken into account in patient on low sodium diet.>

Precautions with respect to environmental hazard are in section 6.6.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

*[Interactions should be presented as brief as possible perhaps with a table of interactions. Only generic names of interacting substances should be used. Only true drug interactions should be included i.e. those which may produce inaccuracies in diagnostic accuracy or interfere with therapeutic efficacy.]*

*[The following statement may be used where appropriate:]*

<No drug–drug interactions have been described to date.>

<No interaction studies have been performed.>

<Paediatric population>

<Interaction studies have only been performed in adults.>

#### **4.6 Fertility, pregnancy and lactation**

Women of childbearing potential

When an administration of radiopharmaceuticals to a woman of childbearing potential is intended, it is important to determine whether or not she is pregnant. Any woman who has missed a period should be



assumed to be pregnant until proven otherwise. If in doubt about her potential pregnancy (if the woman has missed a period, if the period is very irregular, etc.), alternative techniques not using ionising radiation (if there are any) should be offered to the patient.

#### <Contraception in males and females>

##### Pregnancy

*[For radiopharmaceuticals in which pregnancy is not a contraindication:]* Radionuclide procedures carried out on pregnant women also involve radiation dose to the foetus. Only essential investigations should therefore be carried out during pregnancy, when the likely benefit far exceeds the risk incurred by the mother and foetus.

*[If contraindicated:]* The use of {active substance} is contraindicated in pregnancy women due to {reason} (see section 4.3)

##### Breast-feeding

*[The fact whether or not radioactivity will be excreted into breast milk should be mentioned here if applicable.]*

Before administering radiopharmaceuticals to a mother who is breast-feeding consideration should be given to the possibility of delaying the administration of radionuclide until the mother has ceased breastfeeding, and to what is the most appropriate choice of radiopharmaceuticals, bearing in mind the secretion of activity in breast milk. If the administration is considered necessary, breastfeeding should be interrupted for {x} hours and the expressed feeds discarded.

<Close contact with infants should be restricted during> <this period> <[or specifying such period]>.

##### <Fertility>

#### **4.7 Effects on ability to drive and use machines**

<{Invented name} has <no or negligible influence> <minor influence> <moderate influence> <major influence> on the ability to drive and use machines.>

<Not relevant.>

#### **4.8 Undesirable effects**

The following table presents how the frequencies are reflected in this section:

*[Use MedDRA system organ classes (SOCs). The frequency of individual adverse reactions should be stated where possible. The order of presentation should be first adverse reactions like e.g. anaphylaxis (which should be listed with all observed symptoms in the SOC Immune System Disorders/ subheading anaphylactic reactions) then adverse reactions due to radiation exposure as follows a statement about the risk of radiation exposure].*

*[Tabulated list of adverse reactions]*

Very common ( $\geq 1/10$ )
Common ( $\geq 1/100$ to $< 1/10$ )
Uncommon ( $\geq 1/1,000$ to $< 1/100$ )
Rare ( $\geq 1/10,000$ to $< 1/1,000$ )
Very rare ( $< 1/10,000$ )
Not known (cannot be estimated from the available data)

*[The following statement should be included in this section for each radiopharmaceutical:] Exposure to ionising radiation is linked with cancer induction and a potential for development of hereditary defects. [For diagnostic medicinal products:] As the effective dose is [...] mSv when the maximal recommended activity of [...] MBq is administered these adverse reactions are expected to occur with a low probability. [For therapeutic agents:] The radiation dose resulting from therapeutic exposure may result in higher incidence of cancer and mutations [specify if known]. In all cases it is necessary to ensure that the risks of the radiation are less than from the disease itself. <The effective dose is [...] mSv when the maximal recommended activity of [...] MBq is administered.>*

<Paediatric population>

## 4.9 Overdose

*[Brief, appropriate and useful statements should be included. Although overdose is unlikely when a radiopharmaceutical is administered by authorised personnel, the opportunities available to reduce excessive radiation exposure should be outlined. E.g: ]*

In the event of administration of a radiation overdose with [...] the absorbed dose to the patient should be reduced where possible by increasing the elimination of the radionuclide from the body by frequent micturition <and defecation> <or> <by forced diuresis and frequent bladder voiding>. It might be helpful to estimate the effective dose that was applied.

<Paediatric population>

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: {group}, ATC code: {code} <not yet assigned>

<Mechanism of action>

<Pharmacodynamic effects>

<At the chemical concentrations used for diagnostic examinations, [...] does not appear to have any pharmacodynamic activity.>

<[Indication A]>

<[Indication B]>

*[Statements should be appropriate to the concentrations of radiopharmaceutical and excipients administered by the advised route.]*

<Clinical efficacy and safety>

<Paediatric population>

<The European Medicines Agency has waived the obligation to submit the results of studies with {(Invented) Name} in all subsets of the paediatric population in {condition as per Paediatric Investigation Plan (PIP) decision, in the granted indication} (see section 4.2 for information on paediatric use).>

<The European Medicines Agency has deferred the obligation to submit the results of studies with {(Invented) Name} in one or more subsets of the paediatric population in {condition, as per Paediatric Investigation Plan (PIP) decision in the granted indication} (see section 4.2 for information on paediatric use).>

<This medicinal product has been authorised under a so-called ‘conditional approval’ scheme. This means that further evidence on this medicinal product is awaited. The European Medicines Agency will review new information on the product every year and this SmPC will be updated as necessary.>

<This medicinal product has been authorised under ‘exceptional circumstances’. This means that due to <the rarity of the disease> <for scientific reasons> <for ethical reasons> it has not been possible to obtain complete information on this medicinal product. The European Medicines Agency will review any new information which may become available every year and this SmPC will be updated as necessary.>

## 5.2 Pharmacokinetic properties

### Distribution

### Organ uptake

### Elimination

*[State major metabolic pathway for clearance]*

### Half-life

*[State biological half-life and effective half-life (including biological and physical half-lives)]*

*[The provided data should relate entirely to the human species.]*

### <Renal/Hepatic impairment>

<The pharmacokinetics in patients with renal or hepatic impairment has not been characterised.>

### <Paediatric population>

## 5.3 Preclinical safety data

*[The LD<sub>50</sub> should be replaced by a safety factor or NOED.]*

Toxicological studies with [mice/rats] have demonstrated that with a single [IV injection] of [...] and [...] mg/kg no deaths were observed. Toxicity with repeated administration of [...] mg./kg/day over [...] days in ... [rats] ... was not observed. This medicinal product is not intended for regular or continuous administration.

<Mutagenicity studies und long-term carcinogenicity studies have not been carried out.>

<Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.>

<Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.>

<Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows:>

### <Environmental Risk Assessment (ERA)>

## 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

*[Product specific]*

## 6.2 Incompatibilities

*[Product specific]*

<Not applicable.>

<In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.>

<This medicinal product must not be mixed with other medicinal products except those mentioned in section <6.6> <and> <12>.>

## 6.3 Shelf life

*[Product specific]*

<...> <6 months> <...> <1 year> <18 months> <2 years> <30 months> <3 years> <...>

*[Shelf life after radiolabelling and first opening should be provided here.]* After radiolabelling: [...] hours.  
Do not store above [...]°C after radiolabelling.

## 6.4 Special precautions for storage

*[Storage conditions are product specific and are defined during the marketing authorisation procedure.]*

<For storage conditions after <reconstitution> <dilution> <radiolabelling> <first opening> of the medicinal product, see section 6.3.>

Storage of radiopharmaceuticals should be in accordance with national regulation on radioactive materials.

## 6.5 Nature and contents of container <and special equipment for use, administration or implantation>

<Not all pack sizes may be marketed.>

## 6.6 Special precautions for disposal <and other handling>

### General warnings

Radiopharmaceuticals should be received, used and administered only by authorised persons in designated clinical settings. Their receipt, storage, use, transfer and disposal are subject to the regulations and/or appropriate licences of the competent official organisation.

Radiopharmaceuticals should be prepared in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

*[For kits for radiopharmaceutical preparation:]* Contents of the vial are intended only for use in the preparation of [...] and are not to be administered directly to the patient without first undergoing the preparative procedure.

*<Precautions to be taken before handling or administration of the medicinal product>*

*[Any special precautions related to the manipulation or administration of the product by healthcare professionals (including pregnant healthcare professionals) should be mentioned here, with a cross-reference to section 12.]*

<For instructions on <reconstitution> <dilution> <extemporary preparation> of the medicinal product before administration, see sections 12.>

If at any time in the preparation of this product the integrity of this vial is compromised it should not be used.

*[Only for kits for radiopharmaceutical preparation:]* The content of the kit before extemporary preparation is not radioactive. However, after *[e.g. sodium pertechnetate ( $^{99m}\text{Tc}$ ), Ph. Eur.]* is added, adequate shielding of the final preparation must be maintained.

*[This section should include, where appropriate, precautions for relatives, carers and hospital staff:]* The administration of radiopharmaceuticals creates risks for other persons from external radiation or contamination from spill of urine, vomiting etc. Radiation protection precautions in accordance with national regulations must therefore be taken.

*[In case of administration of higher activities:]* This preparation is likely to result in a relatively high radiation dose to most patients. The administration of [...] may result in significant environmental hazard. This may be of concern to the immediate family of those individuals undergoing treatment or the general public depending on the level of activity administered. Suitable precautions in accordance with national regulations should be taken concerning the activity eliminated by the patients in order to avoid any contaminations.

Any unused product or waste material should be disposed of in accordance with local requirements.

## **7. MARKETING AUTHORISATION HOLDER**

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

## **8. MARKETING AUTHORISATION NUMBER(S)**

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

<{DD/MM/YYYY}> <{DD month YYYY}>

## **10. DATE OF REVISION OF THE TEXT**

{MM/YYYY}

## **<11. DOSIMETRY>**

*[Full details of internal radiation dosimetry should be included in this section.]*

*[For radiopharmaceutical kits the physical half-life of the radionuclide with a summary of the energies of the principal particle and photon emissions should be stated in the first paragraph of this section. E.g. for technetium ( $^{99m}\text{Tc}$ ) labelled radiopharmaceuticals:]*

<Technetium ( $^{99m}\text{Tc}$ ) is produced by means of a ( $^{99}\text{Mo}/^{99m}\text{Tc}$ ) generator and decays with the emission of gamma radiation with a mean energy of 140 keV and a half-life of 6.02 hours to technetium ( $^{99}\text{Tc}$ ) which, in view of its long half-life of  $2.13 \times 10^5$  years can be regarded as quasi stable.>

*[In the second paragraph of this section the biokinetic model used for the ICRP calculations of radiation exposure should be stated shortly: ]*

The data listed below are from ICRP [insert volume number of the publication] and are calculated according to the following assumptions: [...]

*[Tabulated data should be included on dosimetry as established from biodistribution studies in man preferably cited from ICRP [volume number]. If for a new radiopharmaceutical a citation from the ICRP is not possible new data should be provided with the respective model. The table should be in decimal numbers.]*

Organ	Dose absorbed per activity administered [mGy/MBq]				
	Adults	15 year old	10 year old	5 year old	1 year old
[...]	[...]	[...]	[...]	[...]	[...]
[...]	[...]	[...]	[...]	[...]	[...]
<b>Effective dose</b> [mSv/MBq]	[...]	[...]	[...]	[...]	[...]

*[The following statement should be included after the table:]*

*[For diagnostic medicinal products:]* The effective dose resulting from the administration of a (maximal recommended) activity of [...] MBq [...] for an adult weighing 70 kg is about [...] mSv. For an administered activity of [...] MBq the typical radiation dose to the target organ *[specify which]* is [...] mGy and the typical radiation dose/doses to the critical organ/organs *[specify which]* is/are Z1 Z2 etc. mGy, respectively.

*[For therapeutic medicinal products:]* Radiation dose to specific organs, which may not be the target organ of therapy, can be influenced significantly by pathophysiological changes induced by the disease process. This should be taken into consideration when using the following information.

*[If easy to calculate for diagnostic medicinal products:]* For an administered activity of [...] MBq the typical radiation dose to the target organ *[specify which]* is [...] mGy and the typical radiation dose/doses to the critical organ/organs *[specify which]* is/are Z1 Z2 etc. mGy, respectively.

## 12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

*[Section 12 is designated to describe the dilution of a ready-to-use (multidose) radiopharmaceutical or the reconstitution of a kit radiopharmaceutical with the eluate of a generator containing the radionuclide. The required quality control should be included if required.]*

*[For ready-to-use radiopharmaceuticals:]*

*[Instructions on the dilution of the ready-to-use radiopharmaceutical before administration could be given here (e. g. with sodium chloride 9 mg/ml solution for injection). Information on the appearance of the diluted parenteral solution should appear here.]*

*[For kits for radiopharmaceutical preparation]*

### Method of preparation

*[Instructions on reconstitution/extemporary preparation of the medicinal product before administration should be included here.]*

*Information on the appearance of the reconstituted parenteral solution should appear here.]*

*[Section 12 is also designated to describe the extemporaneous preparation of radiopharmaceuticals which requires several steps.]*

#### Quality control

*[This section should describe convenient method(s) for quality control of the radiopharmaceutical which could be carried out in any nuclear medicine centre or radiopharmacy, for example, the way to check the rate of radionuclide labelling in case of doubt or when it is performed periodically or systematically.]*

*[Additional requirements for diluents, etc. should appear here.]*

<Detailed information on this medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu>>

## **B. PACKAGE LEAFLET FOR RADIOPHARMACEUTICALS**



## PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

**{{(Invented) name strength pharmaceutical form}}**  
{Active substance(s)}

**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 Nuclear medicine doctor 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 Nuclear medicine doctor who has supervised the procedure.

**In this leaflet:**

1. What X is and what it is used for
2. Before X is used
3. How X is used
4. Possible side effects
5. How X is stored
6. Further information

### **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>

The use of X 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 X IS ADMINISTERED**

**X must not be used**

- <if you are allergic (hypersensitive) to {active substance(s)} or any of the other ingredients of X.>
- <if...>

**Take special care with X**

- <if you are pregnant or believe you may be pregnant >
- <if you are breast-feeding>

#### Children and adolescents

Please speak to your Nuclear medicine doctor <if you are under 18 years old>

#### **<Taking> <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 the images>:

- [product specific]

**<Taking> <Using> X with food and drink**

### **Pregnancy and breast-feeding**

You must inform the Nuclear medicine doctor 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 Nuclear medicine doctor who will supervise the procedure.

If you are pregnant

[product specific]

The Nuclear medicine doctor will only administer this product during pregnancy if a benefit is expected which would outweigh the risks.

If you are breast-feeding

[product specific]

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

Please ask your Nuclear medicine doctor before taking any medicines.

### **Before X 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. >
- <avoid all important physical activity>
- <be fasting for at least 4 hours>
- ...

### **Driving and using machines**

<It is considered unlikely that X will affect your ability to drive or to use machines or <product specific>

<Do not drive <because...>.>

<Do not use any tools or machines.>

### **Important information about some of the ingredients of X**

## **3. HOW WILL X BE USED**

There are strict laws on the use, handling and disposal of radiopharmaceutical products. {(Invented) name} 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.

The Nuclear medicine doctor supervising the procedure will decide on the quantity of X to be used in your case. It will be the smallest 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 (Mega Becquerel, the unit used to express radioactivity).

### **<Use in children>**

In children and adolescents , the quantity to be administered will be adapted to the child's body mass.

### **Administration of X and conduct of the procedure**

X is administered <route of administration>.

<One injection is sufficient to conduct the test that your doctor needs.>

<After injection, you will be offered a drink and asked to urinate immediately preceding the test.>

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.

### **Duration of the procedure**

Your Nuclear medicine doctor 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 Nuclear medicine doctor 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 the Nuclear medicine doctor who supervises the procedure.

### **After administration of X, you should:**

- <avoid any close contact with young children for the {xx} hours following the injection>
- <urinate frequently in order to eliminate the product from your body>
- ...

## **4. POSSIBLE SIDE EFFECTS**

[for diagnostic radiopharmaceuticals only]

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

This administered radiopharmaceutical will deliver <low> amounts of ionising radiation with very low risk of cancer and hereditary abnormalities.

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

[for therapeutic radiopharmaceuticals]

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

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

## **5. HOW X IS STORED**

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.

The information is intended for the specialist only.

X will not be used after the expiry date which is stated on the <label> <carton> <bottle> <...> <after {abbreviation used for expiry date}> <The expiry date refers to the last day of that month.>

X will not be used if it is noticed {description of the visible signs of deterioration}>

## 6. 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

[Product specific]

<Pack size>

[Product specific]

### 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/Rahal}>

Tel: + {Numru tat-telefon}

<{e-mail}>

#### **Danmark**

{Navn}

<{Adresse}

DK-0000 {by}>

Tlf: + {Telefonnummer}

#### **Nederland**

{Naam}

<{Adres}

NL-0000 XX {stad}>

Tel: + {Telefoonnummer}

<{e-mail}>

### Deutschland

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

### Eesti

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

### Ελλάδα

{Όνομα}  
<{Διεύθυνση}  
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}

<{e-mail}>

### Norge

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

### Österreich

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

### Polska

{Nazwa/ Nazwisko:}  
<{Adres:}  
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}  
{Oraș} {Cod poștal} – 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}

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

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}>

#### **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).