ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT
TRADENAME STRENGTH PHARMACEUTICAL FORM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
ACTIVE PHARMACEUTICAL INGREDIENT

2.1 General description

2.2 Qualitative and quantitative composition
EXCIPIENT

3. PHARMACEUTICAL FORM
((The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.)|(The score line is not intended for breaking the tablet.)|(The tablet can be divided into equal doses.))

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
This medicinal product is for diagnostic use only.

4.2 Posology and method of administration
Posology
Paediatric population
Method of administration

4.3 Contraindications

4.4 Special warnings and precautions for use
Traceability
Paediatric population

4.5 Interaction with other medicinal products and other forms of interaction
Paediatric population

4.6 Fertility, pregnancy and lactation
Pregnancy
Breast-feeding
Fertility

4.7 Effects on ability to drive and use machines

4.8 Undesirable effects
Paediatric population

4.9 Overdose
Paediatric population

5. PHARMACOLOGICAL PROPERTIES
ATC CODE

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties
Absorption
Distribution
Biotransformation
Elimination
Linearity/non-linearity
Renal impairment
Hepatic impairment
Elderly
Paediatric population
Other special populations

5.3 Preclinical safety data

Environmental risk assessment (ERA)

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

6.2 Incompatibilities

6.3 Shelf life

6.4 Special precautions for storage

6.5 Nature and contents of container(and special equipment for use, administration or implantation)?

6.6 Special precautions for disposal(and other handling)?

Paediatric population

7. MARKETING AUTHORISATION HOLDER

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2021-06-10

10. DATE OF REVISION OF THE TEXT

11. DOSIMETRY

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS