

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<2.1 General description>

<2.2 Qualitative and quantitative composition>

<Excipient(s) with known effect:>

<For the full list of excipients, see section 6.1.>

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.>

<{X} is indicated in <adults> <neonates> <infants> <children> <adolescents> <aged {x to y}> <years> <months>>.>

4.2 Posology and method of administration

Posology

Paediatric population

<The <safety> <and> <efficacy> of {X} in children aged {x to y} <months> <years> {or any other relevant subsets, e.g. weight, pubertal age, gender} <has> <have> not <yet> been established.>

<No data are available.>

<Currently available data are described in section <4.8> <5.1> <5.2> but no recommendation on a posology can be made.>

<{X} should not be used in children aged {x to y} <years> <months> {or any other relevant subsets, e.g. weight, pubertal age, gender} because of <safety> <efficacy> concern(s).>

<There is no relevant use of {X} <in the paediatric population> <in children aged {x to y} <years>, <months> {or any other relevant subsets, e.g. weight, pubertal age, gender} <in the indication...>.>

<{X} is contraindicated in children aged {x to y} <years> <months> {or any other relevant subsets, e.g. weight, pubertal age, gender} <in the indication...> (see section 4.3).>

Method of administration

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

<For instructions on <reconstitution> <dilution> of the medicinal product before administration, see section <6.6> <and> <12>.>

4.3 Contraindications

<Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1 <or {name of the residue(s)}>.>

4.4 Special warnings and precautions for use

<Paediatric population>

4.5 Interaction with other medicinal products and other forms of interaction

<No interaction studies have been performed.>

<Paediatric population>

<Interaction studies have only been performed in adults.>

4.6 Fertility, pregnancy and lactation

<Pregnancy>

<Breast-feeding>

<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

<Paediatric population>

4.9 Overdose

<Paediatric population>

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

<{{(Invented) Name}} is a biosimilar medicinal product. Detailed information is available on the website of the European Medicines Agency <http://www.ema.europa.eu>.>

<Mechanism of action>

<Pharmacodynamic effects>

<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 Implementation 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 Implementation 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 this medicinal product at least 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

<Absorption>

<Distribution>

<Biotransformation>

<Elimination>

<Linearity/non-linearity>

<Pharmacokinetic/pharmacodynamic relationship(s)>

5.3 Preclinical safety data

<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

<None.>

6.2 Incompatibilities

<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

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

6.4 Special precautions for storage

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

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>

<Use in the paediatric population>

<No special requirements <for disposal>.>

<Any unused medicinal 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

<Date of first authorisation: {DD month YYYY}>

<Date of latest renewal: {DD month YYYY}>

10. DATE OF REVISION OF THE TEXT

<{MM/YYYY}>

<{DD/MM/YYYY}>

<{DD month YYYY}>

<11. DOSIMETRY>

<12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS>

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

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

ANNEX II

- A. <MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND>MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OF THE MARKETING AUTHORISATION**
- <C. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER>**

**A. <MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND>
MANUFACTURER (S) RESPONSIBLE FOR BATCH RELEASE**

<Name and address of the manufacturer(s) of the biological active substance(s)>

{Name and address}>

Name and address of the manufacturer(s) responsible for batch release

{Name and address}

<The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.>

B. CONDITIONS OF THE MARKETING AUTHORISATION

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

<Medicinal product subject to medical prescription.>

<Medicinal product not subject to medical prescription.>

<Medicinal product subject to special medical prescription.>

<Medicinal product subject to restricted medical prescription (see Annex I: Summary of Product Characteristics, section 4.2).>

<Medicinal product subject to special and 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.>

• **OTHER CONDITIONS**

Pharmacovigilance system

The MAH must ensure that the system of pharmacovigilance presented in Module 1.8.1 of the Marketing Authorisation is in place and functioning before and whilst the medicinal product is on the market.

<Risk Management Plan (RMP)>

<The MAH commits to performing the studies and additional pharmacovigilance activities detailed in the Pharmacovigilance Plan, as agreed in version {insert version reference} of the RMP presented in Module 1.8.2 of the Marketing Authorisation and any subsequent updates of the RMP agreed by the Committee for Medicinal Products for Human Use (CHMP).>

As per the CHMP Guideline on Risk Management Systems for medicinal products for human use, any updated RMP should be submitted at the same time as the following Periodic Safety Update Report (PSUR).

In addition, an updated RMP should be submitted:

- When new information is received that may impact on the current Safety Specification, Pharmacovigilance Plan or risk minimisation activities
- Within 60 days of an important (pharmacovigilance or risk minimisation) milestone being reached

- At the request of the European Medicines Agency >

<PSURs>

<Official batch release: in accordance with Article 114 of Directive 2001/83/EC as amended, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.>

<C. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER

The Marketing Authorisation Holder shall complete the following programme of studies within the specified time frame, the results of which shall form the basis of the annual reassessment of the benefit/risk profile.

<Chemical, pharmaceutical and biological aspects>

<Toxicological and pharmacological aspects>

<Clinical aspects>>

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON < THE OUTER PACKAGING> <AND> <THE IMMEDIATE PACKAGING>

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}

{Active substance(s)}

2. STATEMENT OF ACTIVE SUBSTANCE(S)

<This product contains cells of <human> <animal> origin.>

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

5. METHOD AND ROUTE(S) OF ADMINISTRATION

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 sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

<For autologous use only.>

8. EXPIRY DATE

9. SPECIAL STORAGE CONDITIONS

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

{Name and address}

<{tel}>

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

12. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

13. BATCH NUMBER<, DONATION AND PRODUCT CODES>

14. GENERAL CLASSIFICATION FOR SUPPLY

<Medicinal product subject to medical prescription.>
<Medicinal product not subject to medical prescription.>

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

<Justification for not including Braille accepted>

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE MEDICINAL PRODUCT

{(Invented) name strength pharmaceutical form}

{Active substance(s)}

2. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name}

3. EXPIRY DATE

4. BATCH NUMBER<, DONATION AND PRODUCT CODES>

5. OTHER

<For autologous use only.>

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

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

{(Invented) name strength pharmaceutical form}
{Active substance(s)}
{Route of administration}

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

4. BATCH NUMBER<, DONATION AND PRODUCT CODES>

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

6. OTHER

<For autologous use only.>

B. PACKAGE LEAFLET

Package leaflet: Information for the <patient> <user>

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

<Read all of this leaflet carefully before you start <taking> <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> <or nurse>.
- <- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.>
- If you get any side effects, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet>.

<Read all of this leaflet carefully before you start <taking> <using> this medicine because it contains important information for you.

Always <take> <use> this medicine exactly as described in this leaflet or as your <doctor> <,> <or> <pharmacist> <or nurse> <has> <have> told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your <doctor> <,> <or> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse <after {number of} days.>>

What is in this leaflet

1. What X is and what it is used for
2. What you need to know before you <take> <use> X
3. How to <take> <use> X
4. Possible side effects
5. How to store X
6. Contents of the pack and other information

1. What X is and what it is used for

<You must talk to a doctor if you do not feel better or if you feel worse <after {number of} days.>.>

2. What you need to know before you <take> <use> X

Do not <take> <use> X<:>

- <if you are allergic to {active substance(s)} or any of the other ingredients of this medicine (listed in section 6).>

Warnings and precautions

Talk to your doctor <or> <pharmacist> <or nurse> before <taking> <using> X

Children <and teenagers>

Other medicines and X

<Tell your <doctor> <or> <pharmacist> if you are <taking> <using>, have recently <taken> <used> or might <take> <use> any other medicines.>

X with <food> <and> <,> <drink> <and> <alcohol>

Pregnancy <and> <,> breast-feeding <and fertility>

<If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your <doctor> <or> <pharmacist> for advice before taking this medicine.>

Driving and using machines

<X contains {name the excipient(s)}>

3. How to <take> <use> X

<Always <take> <use> this medicine exactly as your doctor <or pharmacist> has told you. Check with your <doctor> <or> <pharmacist> if you are not sure.>

<The recommended dose is...>

<Always <take> <use> this medicine exactly as described in this leaflet or as your <doctor> <,> <or> <pharmacist> <or nurse> <has> <have> told you. Check with your <doctor> <or> <,> <pharmacist> <or nurse> if you are not sure.>

<The recommended dose is...>

<Use in children <and teenagers>>

<The score line is only there to help you break the tablet if you have difficulty swallowing it whole.>

<The tablet can be divided into equal doses.>

<The score line is not intended for breaking the tablet.>

<If you <take> <use> more X than you should>

<If you forget to <take> <use> X>

<Do not take a double dose to make up for a forgotten <tablet> <dose> <...>.>

<If you stop <taking> <using> X>

<If you have any further questions on the use of this medicine, ask your <doctor> <,> <or> <pharmacist> <or nurse>.>

4. Possible side effects

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

<Additional side effects in children <and teenagers>>

If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet.

5. How to store X

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.>

<Do not use this medicine if you notice {description of the visible signs of deterioration}>.>

<Do not throw away any medicines via wastewater <or household waste>. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.>

6. Contents of the pack and other information

What X contains

- The active substance(s) is (are)...
- The other ingredient(s) <(excipient(s))> is (are)...

What X looks like and contents of the pack

Marketing Authorisation Holder and Manufacturer

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

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/Stad}>

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}>

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

Κύπρος

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

Österreich

{Name}
 <{Anschrift}>
 A-0000 {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}>
 {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}>

Latvija

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

United Kingdom

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

Lietuva

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

This leaflet was last revised on <{MM/YYYY}> <{month 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 this medicine at least 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 this medicine every year and this leaflet will be updated as necessary.>

<Other sources of information>

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.>

<This leaflet is available in all EU/EEA languages on the European Medicines Agency website.>

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<The following information is intended for healthcare professionals only:>