EMA/43583/2012

European Medicines Agency decision

P/0009/2012

of 24 January 2012

on the acceptance of a modification of an agreed paediatric investigation plan for darbepoetin alfa (Aranesp and associated names) (EMEA-000329-PIP02-09-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

Only the English text is authentic.

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on the acceptance of a modification of an agreed paediatric investigation plan for darbepoetin alfa (Aranesp and associated names) (EMEA-000329-PIP02-09-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/101/2011 issued on 11 March 2011,

Having regard to the application submitted by Amgen Europe B.V on 3 October 2011 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 December 2011, in accordance with Article 22 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for darbepoetin alfa (Aranesp and associated names), solution for injection, subcutaneous use, intravenous use, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

This decision is addressed to Amgen Europe B.V, Minervum 7061, 4817-ZK, Breda, The Netherlands.

Done at London, 24 January 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/43583/2012

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000329-PIP02-09-M01

Scope of the application

Active substance(s):

Darbepoetin alfa

Invented name:

Aranesp and associated names

Condition(s):

Treatment of anaemia due to chronic disorders

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Intravenous use

Name/corporate name of the PIP applicant:

Amgen Europe B.V

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Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Amgen Europe B.V submitted to the European Medicines Agency on 03 October 2011 an application for modification of the agreed paediatric investigation plan with a waiver as set out in the European Medicines Agency's decision P/101/2011 issued on 11 March 2011.

The application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 12 October 2011.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan in the scope set out in the Annex I of this opinion.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex(es) and appendix.

London, 9 December 2011

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

Annex I

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

1.1. Condition: Treatment of anaemia due to chronic disorders

The waiver applies to:

- adolescents (from 12 to less than 18 years);
- for solution for injection, for subcutaneous or intravenous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are already covered.

2. Paediatric Investigation Plan

2.1. Condition: Treatment of anaemia due to chronic disorders

2.1.1. Indication(s) targeted by the PIP

Treatment of symptomatic anaemia associated with chronic renal failure (CRF)

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From birth to less than 12 years of age.

2.1.3. Pharmaceutical form(s)

Solution for injection

2.1.4. Studies

Area	Number of studies	Description
Quality	1	Study 1 Development of a single-use vial containing 25 µg/mL of darbepoetin alfa.
Non-clinical	0	Not applicable.
Clinical	3	Study 2 Open label, single-arm trial to evaluate safety and tolerability, pharmacokinetics and pharmacodynamics of darbepoetin alfa in children from birth to less than 1 year of age with anaemia due to chronic kidney disease (CKD). Study 3 Double blind, randomised, multicentre trial to evaluate efficacy of darbepoetin alfa at different dosage regimes in children from 1 to less than 18 years of age with anaemia due to chronic kidney disease (CKD). Study 4 Non-interventional, prospective observational registry study to evaluate safety of darbepoetin alfa in children from birth to less than 17 years of age with anaemia due to chronic kidney disease (CKD).

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By December 2016.
Deferral for one or more studies contained in the paediatric investigation plan:	No

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

Treatment of anaemia due to chronic disorders

Authorised indications:

- Treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adults and paediatric patients.
- Treatment of symptomatic anaemia in adult cancer patients with non-myeloid malignancies receiving chemotherapy.

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/01/185/001	Aranesp	10 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.4 ml (25 µg/ml)	1 pre-filled syringe
EU/1/01/185/002	Aranesp	10 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.4 ml (25 µg/ml)	4 pre-filled syringes
EU/1/01/185/003	Aranesp	15 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.375 ml (40 µg/ml)	1 pre-filled syringe
EU/1/01/185/004	Aranesp	15 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.375 ml (40 µg/ml)	4 pre-filled syringes
EU/1/01/185/005	Aranesp	20 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.5 ml (40 µg/ml)	1 pre-filled syringe
EU/1/01/185/006	Aranesp	20 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.5 ml (40 µg/ml)	4 pre-filled syringes
EU/1/01/185/007	Aranesp	30 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (100 µg/ml)	1 pre-filled syringe
EU/1/01/185/008	Aranesp	30 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (100 µg/ml)	4 pre-filled syringes
EU/1/01/185/009	Aranesp	40 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.4 ml (100 µg/ml)	1 pre-filled syringe
EU/1/01/185/010	Aranesp	40 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.4 ml (100 µg/ml)	4 pre-filled syringes
EU/1/01/185/011	Aranesp	50 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.5 ml (100 µg/ml)	1 pre-filled syringe
EU/1/01/185/012	Aranesp	50 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.5 ml (100 µg/ml)	4 pre-filled syringes
EU/1/01/185/013	Aranesp	60 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (200 µg/ml)	1 pre-filled syringe

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/01/185/014	Aranesp	60 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (200 µg/ml)	4 pre-filled syringe
EU/1/01/185/015	Aranesp	80 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.4 ml (200 µg/ml)	1 pre-filled syringe
EU/1/01/185/016	Aranesp	80 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.4 ml (200 µg/ml)	4 pre-filled syringes
EU/1/01/185/017	Aranesp	100 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.5 ml (200 µg/ml)	1 pre-filled syringe
EU/1/01/185/018	Aranesp	100 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.5 ml (200 µg/ml)	4 pre-filled syringes
EU/1/01/185/019	Aranesp	150 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (500 µg/ml)	1 pre-filled syringe
EU/1/01/185/020	Aranesp	150 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (500 µg/ml)	4 pre-filled syringes
EU/1/01/185/021	Aranesp	300 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.6 ml (500 µg/ml)	1 pre-filled syringe
EU/1/01/185/022	Aranesp	300 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.6 ml (500 µg/ml)	4 pre-filled syringes
EU/1/01/185/031	Aranesp	500 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	1 ml (500 µg/ml)	1 pre-filled syringe
EU/1/01/185/032	Aranesp	500 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	1 ml (500 µg/ml)	4 pre-filled syringes
EU/1/01/185/033	Aranesp	10 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.4 ml (25 µg/ml)	1 pre-filled syringe (non-blister)
EU/1/01/185/034	Aranesp	15 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.375 ml (40 µg/ml)	1 pre-filled syringe (non-blister)
EU/1/01/185/035	Aranesp	20 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.5 ml (40 µg/ml)	1 pre-filled syringe (non-blister)
EU/1/01/185/036	Aranesp	30 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (100 µg/ml)	1 pre-filled syringe (non-blister)

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/01/185/037	Aranesp	40 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.4 ml (100 µg/ml)	1 pre-filled syringe (non-blister)
EU/1/01/185/038	Aranesp	50 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.5 ml (100 µg/ml)	1 pre-filled syringe (non-blister)
EU/1/01/185/039	Aranesp	60 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (200 µg/ml)	1 pre-filled syringe (non-blister)
EU/1/01/185/040	Aranesp	80 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.4 ml (200 µg/ml)	1 pre-filled syringe (non-blister)
EU/1/01/185/041	Aranesp	100 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.5 ml (200 µg/ml)	1 pre-filled syringe (non-blister)
EU/1/01/185/042	Aranesp	150 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.3 ml (500 µg/ml)	1 pre-filled syringe (non-blister)
EU/1/01/185/043	Aranesp	300 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.6 ml (500 µg/ml)	1 pre-filled syringe (non-blister)
EU/1/01/185/044	Aranesp	500 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	1 ml (500 µg/ml)	1 pre-filled syringe (non-blister)
EU/1/01/185/045	Aranesp	10 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.4 ml (25 µg/ml)	1 pre-filled pen
EU/1/01/185/046	Aranesp	15 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.375 ml (40 µg/ml)	1 pre-filled pen
EU/1/01/185/047	Aranesp	20 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.5 ml (40 µg/ml)	1 pre-filled pen
EU/1/01/185/048	Aranesp	30 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.3 ml (100 µg/ml)	1 pre-filled pen
EU/1/01/185/049	Aranesp	40 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.4 ml (100 µg/ml)	1 pre-filled pen

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/01/185/050	Aranesp	50 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.5 ml (100 µg/ml)	1 pre-filled pen
EU/1/01/185/051	Aranesp	60 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.3 ml (200 µg/ml)	1 pre-filled pen
EU/1/01/185/052	Aranesp	80 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.4 ml (200 µg/ml)	1 pre-filled pen
EU/1/01/185/053	Aranesp	100 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.5 ml (200 µg/ml)	1 pre-filled pen
EU/1/01/185/054	Aranesp	150 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.3 ml (500 µg/ml)	1 pre-filled pen
EU/1/01/185/055	Aranesp	300 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.6 ml (500 µg/ml)	1 pre-filled pen
EU/1/01/185/056	Aranesp	500 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	1 ml (500 µg/ml)	1 pre-filled pen
EU/1/01/185/057	Aranesp	10 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.4 ml (25 µg/ml)	4 pre-filled pens
EU/1/01/185/058	Aranesp	15 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.375 ml (40 µg/ml)	4 pre-filled pens
EU/1/01/185/059	Aranesp	20 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.5 ml (40 µg/ml)	4 pre-filled pens
EU/1/01/185/060	Aranesp	30 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.3 ml (100 µg/ml)	4 pre-filled pens
EU/1/01/185/061	Aranesp	40 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.4 ml (100 µg/ml)	4 pre-filled pens
EU/1/01/185/062	Aranesp	50 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.5 ml (100 µg/ml)	4 pre-filled pens
EU/1/01/185/063	Aranesp	60 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.3 ml (200 µg/ml)	4 pre-filled pens
EU/1/01/185/064	Aranesp	80 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.4 ml (200 µg/ml)	4 pre-filled pens
EU/1/01/185/065	Aranesp	100 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.5 ml (200 µg/ml)	4 pre-filled pens
EU/1/01/185/066	Aranesp	150 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.3 ml (500 µg/ml)	4 pre-filled pens

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/01/185/067	Aranesp	300 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.6 ml (500 µg/ml)	4 pre-filled pens
EU/1/01/185/068	Aranesp	500 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	1 ml (500 µg/ml)	4 pre-filled pens
EU/1/01/185/069	Aranesp	130 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.65 ml (200 µg/ml)	1 pre-filled syringe
EU/1/01/185/070	Aranesp	130 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.65 ml (200 µg/ml)	4 pre-filled syringes
EU/1/01/185/071	Aranesp	130 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass)	0.65 ml (200 µg/ml)	1 pre-filled syringe (non-blister)
EU/1/01/185/072	Aranesp	130 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.65 ml (200 µg/ml)	1 pre-filled pen
EU/1/01/185/073	Aranesp	130 µg	Solution for injection	Subcutaneous use	pre-filled pen (glass) (SureClick)	0.65 ml (200 µg/ml)	4 pre-filled pens
EU/1/01/185/074	Aranesp	10 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.4 ml (25 µg/ml)	1 pre-filled syringe with needle guard
EU/1/01/185/075	Aranesp	10 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.4 ml (25 µg/ml)	4 pre-filled syringes with needle guard
EU/1/01/185/076	Aranesp	15 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.375 ml (40 µg/ml)	1 pre-filled syringe with needle guard
EU/1/01/185/077	Aranesp	15 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.375 ml (40 µg/ml)	4 pre-filled syringes with needle guard
EU/1/01/185/078	Aranesp	20 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.5 ml (40 µg/ml)	1 pre-filled syringe with needle guard
EU/1/01/185/079	Aranesp	20 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.5 ml (40 µg/ml)	4 pre-filled syringes with needle guard

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/01/185/080	Aranesp	30 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.3 ml (100 µg/ml)	1 pre-filled syringe with needle guard
EU/1/01/185/081	Aranesp	30 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.3 ml (100 µg/ml)	4 pre-filled syringes with needle guard
EU/1/01/185/082	Aranesp	40 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.4 ml (100 µg/ml)	1 pre-filled syringe with needle guard
EU/1/01/185/083	Aranesp	40 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.4 ml (100 µg/ml)	4 pre-filled syringes with needle guard
EU/1/01/185/084	Aranesp	50 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.5 ml (100 µg/ml)	1 pre-filled syringe with needle guard
EU/1/01/185/085	Aranesp	50 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.5 ml (100 µg/ml)	4 pre-filled syringes with needle guard
EU/1/01/185/086	Aranesp	60 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.3 ml (200 µg/ml)	1 pre-filled syringe with needle guard
EU/1/01/185/087	Aranesp	60 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.3 ml (200 µg/ml)	4 pre-filled syringes with needle guard
EU/1/01/185/088	Aranesp	80 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.4 ml (200 µg/ml)	1 pre-filled syringe with needle guard
EU/1/01/185/089	Aranesp	80 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.4 ml (200 µg/ml)	4 pre-filled syringes with needle guard
EU/1/01/185/090	Aranesp	100 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.5 ml (200 µg/ml)	1 pre-filled syringe with needle guard

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/01/185/091	Aranesp	100 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.5 ml (200 µg/ml)	4 pre-filled syringes with needle guard
EU/1/01/185/092	Aranesp	130 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.65 ml (200 µg/ml)	1 pre-filled syringe with needle guard
EU/1/01/185/093	Aranesp	130 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.65 ml (200 µg/ml)	4 pre-filled syringes with needle guard
EU/1/01/185/094	Aranesp	150 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.3 ml (500 µg/ml)	1 pre-filled syringe with needle guard
EU/1/01/185/095	Aranesp	150 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.3 ml (500 µg/ml)	4 pre-filled syringes with needle guard
EU/1/01/185/096	Aranesp	300 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.6 ml (500 µg/ml)	1 pre-filled syringe with needle guard
EU/1/01/185/097	Aranesp	300 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	0.6 ml (500 µg/ml)	4 pre-filled syringes with needle guard
EU/1/01/185/098	Aranesp	500 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	1 ml (500 µg/ml)	1 pre-filled syringe with needle guard
EU/1/01/185/099	Aranesp	500 µg	Solution for injection	Subcutaneous or intravenous use	pre-filled syringe (glass) with needle guard	1 ml (500 µg/ml)	4 pre-filled syringes with needle guard
EU/1/01/185/100	Aranesp	25 µg	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (25 µg/ml)	1 vial
EU/1/01/185/101	Aranesp	25 µg	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (25 µg/ml)	4 vials
EU/1/01/185/102	Aranesp	40 µg	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (40 µg/ml)	1 vial

EU Number	Invented name	Strength	Pharmaceutical Form	Route of Administration	Packaging	Content	Package size
EU/1/01/185/103	Aranesp	40 µg	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (40 µg/ml)	4 vials
EU/1/01/185/104	Aranesp	60 µg	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (60 µg/ml)	1 vial
EU/1/01/185/105	Aranesp	60 µg	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (60 µg/ml)	4 vials
EU/1/01/185/106	Aranesp	100 µg	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (100 µg/ml)	1 vial
EU/1/01/185/107	Aranesp	100 µg	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (100 µg/ml)	4 vials
EU/1/01/185/108	Aranesp	200 µg	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (200 µg/ml)	1 vial
EU/1/01/185/109	Aranesp	200 µg	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (200 µg/ml)	4 vials
EU/1/01/185/110	Aranesp	300 µg	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (300 µg/ml)	1 vial
EU/1/01/185/111	Aranesp	300 µg	Solution for injection	Subcutaneous or intravenous use	vial (glass)	1 ml (300 µg/ml)	4 vials