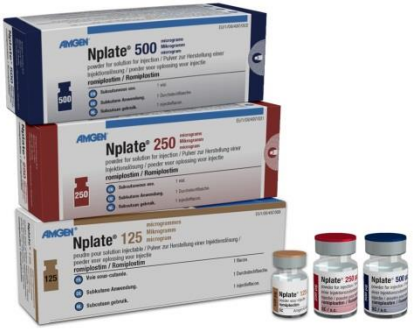
Nplate® (romiplostim) Dose Calculator

Handling Guidance

- Nplate® can only be reconstituted with preservative-free sterile water for injections.
  DO NOT use sodium chloride solution for injection or bacteriostatic water for reconstitution of Nplate®.
- Nplate® is available:
  - in 125, 250, or 500 mcg on its own as a powder for solution for injections (paediatric and adult patients)
  - in 250 or 500 mcg as a complete reconstitution pack including Nplate® powder for solution for injections and a pre-filled syringe with sterile water for injections (adult patients).
- Refrigerate (2° to 8°C) Nplate® and protect from light. Do not freeze.
- Nplate® should be used immediately after reconstitution. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 25°C or 24 hours in a refrigerator (2° to 8°C).
- Reconstituted Nplate® must also be protected from light.
- Any unused product or waste material should be disposed of in accordance with local requirements.
- Nplate® is a protein – **DO NOT SHAKE OR VIGOROUSLY AGITATE** the vial during reconstitution.



Steps for Reconstitution, Dilution (if Required) and Administration

Reconstitution:

Sterile water for injections only should be used when reconstituting the medicinal product. DO NOT use sodium chloride solutions for injection or bacteriostatic water for reconstitution of Nplate®.

1. Nplate® should be reconstituted in accordance with good aseptic practice.
2. **Sterile water for injections** should be injected into the vial.
3. The vial contents may be swirled gently and inverted during dissolution. **The vial should not be shaken or vigorously agitated.** Generally, dissolution of Nplate® takes less than 2 minutes.
4. Visually inspect the solution for particulate matter and discolouration before administration.
   - The reconstituted solution should be clear and colourless.
   - The reconstituted solution should not be administered if particulate matter and/or discolouration are observed.

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

Vial content:

Nplate® single-use vial	Total vial content of romiplostim		Volume of sterile water for injections		Deliverable product and volume	Final concentration
125 mcg	230 mcg	add	0.44 mL	=	125 mcg in 0.25 mL	500 mcg/mL
250 mcg	375 mcg	add	0.72 mL	=	250 mcg in 0.50 mL	500 mcg/mL
500 mcg	625 mcg	add	1.20 mL	=	500 mcg in 1.00 mL	500 mcg/mL

Steps for Reconstitution, Dilution (if Required) and Administration

Dilution (required when the calculated individual patient dose is less than 23 mcg):
Preservative-free, sterile, sodium chloride 9 mg/mL (0.9%) solution for injection only must be used for dilution. DO NOT use dextrose (5%) in water or sterile water for injection for dilution.

Initial reconstitution of Nplate® with designated volumes of sterile water for injections results in a concentration of 500 mcg/mL in all vial sizes (see previous page and the vial content table). If the calculated individual patient dose is less than 23 mcg, an additional dilution step to 125 mcg/mL with **preservative-free, sterile, sodium chloride 9 mg/mL (0.9%) solution for injection** is required to ensure accurate dosing (see table below).

Dilution guidelines (refer to dose calculator for total injection volume to administer using the diluted concentration):

Nplate® single-use vial	Add this volume of preservative-free, sterile, sodium chloride 9 mg/mL (0.9%) solution for injection to the **reconstituted vial**	Concentration **after** dilution
125 mcg	1.38 mL	125 mcg/mL
250 mcg	2.25 mL	125 mcg/mL
500 mcg	3.75 mL	125 mcg/mL

Storage of reconstituted and diluted Nplate®:

After reconstitution: chemical and physical in-use stability has been demonstrated for 24 hours at 25°C and for 24 hours at 2° to 8°C, when protected from light and **kept in the original vial**.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 25°C or 24 hours in a refrigerator (2° to 8°C), protected from light.

After dilution: chemical and physical in-use stability has been demonstrated for 4 hours at 25°C when the diluted product was held in a disposable syringe, or 4 hours in a refrigerator (2° to 8°C) when the diluted product was held in the original vial.

From a microbiological point of view, the diluted medicinal product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 4 hours at 25°C in disposable syringes, or 4 hours in a refrigerator (2° to 8°C) in the original vials, protected from light.

How to Calculate Nplate® Dose

Calculate initial dose:

1. Initial dose for Nplate® is 1 mcg/kg based on **actual body weight at initiation of therapy**.
2. Determine patient's weight in kilograms.
3. The individual patient dose does not have to be determined in order to use the dosing calculator.
4. Refer to dosing calculator windows on the following pages to achieve total injection volume required according to patient's weight (kg) and dose in mcg/kg.

Subsequent doses:

1. Determine patient's platelet count and previous week's dose.
2. Refer to dose adjustment table to determine how to adjust dose in mcg/kg based on changes in platelet counts.
3. In paediatric patients, future dose adjustments are based on changes in platelet counts **and** changes in body weight. Reassessment of body weight is recommended every 12 weeks.
4. Refer to dosing calculator windows on the following pages to achieve total injection volume required according to patient's weight (kg) and dose in mcg/kg.
5. Platelet counts should be assessed weekly until a stable platelet count ($\geq 50 \times 10^9$/L for at least 4 weeks without dose adjustment) has been achieved. Platelet counts should be assessed monthly thereafter and appropriate dose adjustments made as per the dose adjustment table in order to maintain platelet counts within the recommended range.

How to Calculate Nplate® Dose

Patients weighing 6 kg to 22 kg
Volumes to administer when no additional dilution is required

Patient weight (kg)	Dose (mcg/kg)									
	1 mcg/kg	2 mcg/kg	3 mcg/kg	4 mcg/kg	5 mcg/kg	6 mcg/kg	7 mcg/kg	8 mcg/kg	9 mcg/kg	10 mcg/kg

Total injection volume (mL) required for individual patient dose

Patients weighing 6 kg to 22 kg
Volumes to administer after additional dilution to 125 mcg/mL

Patient weight (kg)	Dose (mcg/kg)									
	1 mcg/kg	2 mcg/kg	3 mcg/kg	4 mcg/kg	5 mcg/kg	6 mcg/kg	7 mcg/kg	8 mcg/kg	9 mcg/kg	10 mcg/kg

Total injection volume (mL) required for individual patient dose

When additional dilution is required, please refer to the window on the right on this page to achieve total injection volume required using the diluted product at 125 mcg/mL. Please note that calculation of individual patient dose is not required when using the dosing calculator window.

Individual patient dose (mcg) = patient's initial weight (kg) × dose in mcg/kg

$$\text{Injection volume in mL*} = \frac{\text{individual patient dose (mcg)}}{\text{500 mcg/mL**}}$$

*Round volume to the nearest hundredth mL

**Or 125 mcg/mL, if additional dilution required

= Additional dilution required

= One 250 mcg vial

= One 125 mcg vial

Dilution guidelines:

Nplate® single-use vial	Add this volume of preservative-free, sterile, sodium chloride 9 mg/mL (0.9%) solution for injection to the **reconstituted vial**	Concentration **after** dilution
125 mcg	1.38 mL	125 mcg/mL
250 mcg	2.25 mL	125 mcg/mL
500 mcg	3.75 mL	125 mcg/mL

PULL

Patients weighing 6 kg to 22 kg

Volumes to administer when no additional dilution is required

6	*	*	*	0.05	0.06	0.07	0.08	0.10	0.11	0.12
7	*	*	*	0.06	0.07	0.08	0.10	0.11	0.13	0.14
8	*	*	0.05	0.06	0.08	0.10	0.11	0.13	0.14	0.16
9	*	*	0.05	0.07	0.09	0.11	0.13	0.14	0.16	0.18
10	*	*	0.06	0.08	0.10	0.12	0.14	0.16	0.18	0.20
11	*	*	0.07	0.09	0.11	0.13	0.15	0.18	0.20	0.22
12	*	0.05	0.07	0.10	0.12	0.14	0.17	0.19	0.22	0.24
13	*	0.05	0.08	0.10	0.13	0.16	0.18	0.21	0.23	0.26
14	*	0.06	0.08	0.11	0.14	0.17	0.20	0.22	0.25	0.28
15	*	0.06	0.09	0.12	0.15	0.18	0.21	0.24	0.27	0.30
16	*	0.06	0.10	0.13	0.16	0.19	0.22	0.26	0.29	0.32
17	*	0.07	0.10	0.14	0.17	0.20	0.24	0.27	0.31	0.34
18	*	0.07	0.11	0.14	0.18	0.22	0.25	0.29	0.32	0.36
19	*	0.08	0.11	0.15	0.19	0.23	0.27	0.30	0.34	0.38
20	*	0.08	0.12	0.16	0.20	0.24	0.28	0.32	0.36	0.40
21	*	0.08	0.13	0.17	0.21	0.25	0.29	0.34	0.38	0.42
22	*	0.09	0.13	0.18	0.22	0.26	0.31	0.35	0.40	0.44

Patients weighing 6 kg to 22 kg

Volumes to administer after additional dilution to 125 mcg/mL

6	0.05	0.10	0.14
7	0.06	0.11	0.17
8	0.06	0.13	
9	0.07	0.14	
10	0.08	0.16	
11	0.09	0.18	
12	0.10		
13	0.10		
14	0.11		
15	0.12		
16	0.13		
17	0.14		
18	0.14		
19	0.15		
20	0.16		
21	0.17		
22	0.18		

FOLD

PULL

Patients weighing 23 kg to 45 kg

23	0.05	0.09	0.14	0.18	0.23	0.28	0.32	0.37	0.41	0.46
24	0.05	0.10	0.14	0.19	0.24	0.29	0.34	0.38	0.43	0.48
25	0.05	0.10	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50
26	0.05	0.10	0.16	0.21	0.26	0.31	0.36	0.42	0.47	0.52
27	0.05	0.11	0.16	0.22	0.27	0.32	0.38	0.43	0.49	0.54
28	0.06	0.11	0.17	0.22	0.28	0.34	0.39	0.45	0.50	0.56
29	0.06	0.12	0.17	0.23	0.29	0.35	0.41	0.46	0.52	0.58
30	0.06	0.12	0.18	0.24	0.30	0.36	0.42	0.48	0.54	0.60
31	0.06	0.12	0.19	0.25	0.31	0.37	0.43	0.50	0.56	0.62
32	0.06	0.13	0.19	0.26	0.32	0.38	0.45	0.51	0.58	0.64
33	0.07	0.13	0.20	0.26	0.33	0.40	0.46	0.53	0.59	0.66
34	0.07	0.14	0.20	0.27	0.34	0.41	0.48	0.54	0.61	0.68
35	0.07	0.14	0.21	0.28	0.35	0.42	0.49	0.56	0.63	0.70
36	0.07	0.14	0.22	0.29	0.36	0.43	0.50	0.58	0.65	0.72
37	0.07	0.15	0.22	0.30	0.37	0.44	0.52	0.59	0.67	0.74
38	0.08	0.15	0.23	0.30	0.38	0.46	0.53	0.61	0.68	0.76
39	0.08	0.16	0.23	0.31	0.39	0.47	0.55	0.62	0.70	0.78
40	0.08	0.16	0.24	0.32	0.40	0.48	0.56	0.64	0.72	0.80
41	0.08	0.16	0.25	0.33	0.41	0.49	0.57	0.66	0.74	0.82
42	0.08	0.17	0.25	0.34	0.42	0.50	0.59	0.67	0.76	0.84
43	0.09	0.17	0.26	0.34	0.43	0.52	0.60	0.69	0.77	0.86
44	0.09	0.18	0.26	0.35	0.44	0.53	0.62	0.70	0.79	0.88
45	0.09	0.18	0.27	0.36	0.45	0.54	0.63	0.72	0.81	0.90

Patients weighing 46 kg to 68 kg

46	0.09	0.18	0.28	0.37	0.46	0.55	0.64	0.74	0.83	0.92
47	0.09	0.19	0.28	0.38	0.47	0.56	0.66	0.75	0.85	0.94
48	0.10	0.19	0.29	0.38	0.48	0.58	0.67	0.77	0.86	0.96
49	0.10	0.20	0.29	0.39	0.49	0.59	0.69	0.78	0.88	0.98
50	0.10	0.20	0.30	0.40	0.50	0.60	0.70	0.80	0.90	1.00
51	0.10	0.20	0.31	0.41	0.51	0.61	0.71	0.82	0.92	1.02
52	0.10	0.21	0.31	0.42	0.52	0.62	0.73	0.83	0.94	1.04
53	0.11	0.21	0.32	0.42	0.53	0.64	0.74	0.85	0.95	1.06
54	0.11	0.22	0.32	0.43	0.54	0.65	0.76	0.86	0.97	1.08
55	0.11	0.22	0.33	0.44	0.55	0.66	0.77	0.88	0.99	1.10
56	0.11	0.22	0.34	0.45	0.56	0.67	0.78	0.90	1.01	1.12
57	0.11	0.23	0.34	0.46	0.57	0.68	0.80	0.91	1.03	1.14
58	0.12	0.23	0.35	0.46	0.58	0.70	0.81	0.93	1.04	1.16
59	0.12	0.24	0.35	0.47	0.59	0.71	0.83	0.94	1.06	1.18
60	0.12	0.24	0.36	0.48	0.60	0.72	0.84	0.96	1.08	1.20
61	0.12	0.24	0.37	0.49	0.61	0.73	0.85	0.98	1.10	1.22
62	0.12	0.25	0.37	0.50	0.62	0.74	0.87	0.99	1.12	1.24
63	0.13	0.25	0.38	0.50	0.63	0.76	0.88	1.01	1.13	1.26
64	0.13	0.26	0.38	0.51	0.64	0.77	0.90	1.02	1.15	1.28
65	0.13	0.26	0.39	0.52	0.65	0.78	0.91	1.04	1.17	1.30
66	0.13	0.26	0.40	0.53	0.66	0.79	0.92	1.06	1.19	1.32
67	0.13	0.27	0.40	0.54	0.67	0.80	0.94	1.07	1.21	1.34
68	0.14	0.27	0.41	0.54	0.68	0.82	0.95	1.09	1.22	1.36

FOLD

FOLD

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How to Calculate Nplate® Dose

Volumes to administer for patients weighing 23 kg and above do not require additional dilution

Patients weighing 23 kg to 45 kg

Patient weight (kg)	Dose (mcg/kg)									
	1 mcg/kg	2 mcg/kg	3 mcg/kg	4 mcg/kg	5 mcg/kg	6 mcg/kg	7 mcg/kg	8 mcg/kg	9 mcg/kg	10 mcg/kg

Total injection volume (mL) required for individual patient dose

Patients weighing 46 kg to 68 kg

Patient weight (kg)	Dose (mcg/kg)									
	1 mcg/kg	2 mcg/kg	3 mcg/kg	4 mcg/kg	5 mcg/kg	6 mcg/kg	7 mcg/kg	8 mcg/kg	9 mcg/kg	10 mcg/kg

Total injection volume (mL) required for individual patient dose

Individual patient dose (mcg) = patient's initial weight (kg) × dose in mcg/kg

Injection volume in mL* = $\frac{\text{individual patient dose (mcg)}}{\text{500 mcg/mL}}$

*Round volume to the nearest hundredth mL

- = One 125 mcg vial
- = One 250 mcg vial
- = One 250 mcg vial + one 125 mcg vial
- = One 500 mcg vial
- = One 500 mcg vial + one 125 mcg vial
- = One 500 mcg vial + one 250 mcg vial

FOLD and GLUE

FOLD and GLUE

FOLD

FOLD

How to Calculate Nplate® Dose

Volumes to administer for patients weighing 23 kg and above do not require additional dilution

Patients weighing 69 kg to 91 kg

Patient weight (kg)	Dose (mcg/kg)									
	1 mcg/kg	2 mcg/kg	3 mcg/kg	4 mcg/kg	5 mcg/kg	6 mcg/kg	7 mcg/kg	8 mcg/kg	9 mcg/kg	10 mcg/kg

Total injection volume (mL) required for individual patient dose

Patients weighing 92 kg to 114 kg

Patient weight (kg)	Dose (mcg/kg)									
	1 mcg/kg	2 mcg/kg	3 mcg/kg	4 mcg/kg	5 mcg/kg	6 mcg/kg	7 mcg/kg	8 mcg/kg	9 mcg/kg	10 mcg/kg

Total injection volume (mL) required for individual patient dose

Individual patient dose (mcg) = patient's initial weight (kg) × dose in mcg/kg

Injection volume in mL* = $\frac{\text{individual patient dose (mcg)}}{\text{500 mcg/mL}}$

*Round volume to the nearest hundredth mL

- = One 125 mcg vial
- = One 250 mcg vial
- = One 250 mcg vial + one 125 mcg vial
- = One 500 mcg vial
- = One 500 mcg vial + one 125 mcg vial
- = One 500 mcg vial + one 250 mcg vial
- = One 500 mcg vial + one 250 mcg vial + one 125 mcg vial
- = Two 500 mcg vials
- = Two 500 mcg vials + one 125 mcg vial
- = Two 500 mcg vials + one 250 mcg vial

FOLD and GLUE

PULL

Patients weighing 69 kg to 91 kg

69	0.14	0.28	0.41	0.55	0.69	0.83	0.97	1.10	1.24	1.38
70	0.14	0.28	0.42	0.56	0.70	0.84	0.98	1.12	1.26	1.40
71	0.14	0.28	0.43	0.57	0.71	0.85	0.99	1.14	1.28	1.42
72	0.14	0.29	0.43	0.58	0.72	0.86	1.01	1.15	1.30	1.44
73	0.15	0.29	0.44	0.58	0.73	0.88	1.02	1.17	1.31	1.46
74	0.15	0.30	0.44	0.59	0.74	0.89	1.04	1.18	1.33	1.48
75	0.15	0.30	0.45	0.60	0.75	0.90	1.05	1.20	1.35	1.50
76	0.15	0.30	0.46	0.61	0.76	0.91	1.06	1.22	1.37	1.52
77	0.15	0.31	0.46	0.62	0.77	0.92	1.08	1.23	1.39	1.54
78	0.16	0.31	0.47	0.62	0.78	0.94	1.09	1.25	1.40	1.56
79	0.16	0.32	0.47	0.63	0.79	0.95	1.11	1.26	1.42	1.58
80	0.16	0.32	0.48	0.64	0.80	0.96	1.12	1.28	1.44	1.60
81	0.16	0.32	0.49	0.65	0.81	0.97	1.13	1.30	1.46	1.62
82	0.16	0.33	0.49	0.66	0.82	0.98	1.15	1.31	1.48	1.64
83	0.17	0.33	0.50	0.66	0.83	1.00	1.16	1.33	1.49	1.66
84	0.17	0.34	0.50	0.67	0.84	1.01	1.18	1.34	1.51	1.68
85	0.17	0.34	0.51	0.68	0.85	1.02	1.19	1.36	1.53	1.70
86	0.17	0.34	0.52	0.69	0.86	1.03	1.20	1.38	1.55	1.72
87	0.17	0.35	0.52	0.70	0.87	1.04	1.22	1.39	1.57	1.74
88	0.18	0.35	0.53	0.70	0.88	1.06	1.23	1.41	1.58	1.76
89	0.18	0.36	0.53	0.71	0.89	1.07	1.25	1.42	1.60	1.78
90	0.18	0.36	0.54	0.72	0.90	1.08	1.26	1.44	1.62	1.80
91	0.18	0.36	0.55	0.73	0.91	1.09	1.27	1.46	1.64	1.82

Patients weighing 92 kg to 114 kg

92	0.18	0.37	0.55	0.74	0.92	1.10	1.29	1.47	1.66	1.84
93	0.19	0.37	0.56	0.74	0.93	1.12	1.30	1.49	1.67	1.86
94	0.19	0.38	0.56	0.75	0.94	1.13	1.32	1.50	1.69	1.88
95	0.19	0.38	0.57	0.76	0.95	1.14	1.33	1.52	1.71	1.90
96	0.19	0.38	0.58	0.77	0.96	1.15	1.34	1.54	1.73	1.92
97	0.19	0.39	0.58	0.78	0.97	1.16	1.36	1.55	1.75	1.94
98	0.20	0.39	0.59	0.78	0.98	1.18	1.37	1.57	1.76	1.96
99	0.20	0.40	0.59	0.79	0.99	1.19	1.39	1.58	1.78	1.98
100	0.20	0.40	0.60	0.80	1.00	1.20	1.40	1.60	1.80	2.00
101	0.20	0.40	0.61	0.81	1.01	1.21	1.41	1.62	1.82	2.02
102	0.20	0.41	0.61	0.82	1.02	1.22	1.43	1.63	1.84	2.04
103	0.21	0.41	0.62	0.82	1.03	1.24	1.44	1.65	1.85	2.06
104	0.21	0.42	0.62	0.83	1.04	1.25	1.46	1.66	1.87	2.08
105	0.21	0.42	0.63	0.84	1.05	1.26	1.47	1.68	1.89	2.10
106	0.21	0.42	0.64	0.85	1.06	1.27	1.48	1.70	1.91	2.12
107	0.21	0.43	0.64	0.86	1.07	1.28	1.50	1.71	1.93	2.14
108	0.22	0.43	0.65	0.86	1.08	1.30	1.51	1.73	1.94	2.16
109	0.22	0.44	0.65	0.87	1.09	1.31	1.53	1.74	1.96	2.18
110	0.22	0.44	0.66	0.88	1.10	1.32	1.54	1.76	1.98	2.20
111	0.22	0.44	0.67	0.89	1.11	1.33	1.55	1.78	2.00	2.22
112	0.22	0.45	0.67	0.90	1.12	1.34	1.57	1.79	2.02	2.24
113	0.23	0.45	0.68	0.90	1.13	1.36	1.58	1.81	2.03	2.26
114	0.23	0.46	0.68	0.91	1.14	1.37	1.60	1.82	2.05	2.28

PULL

Patients weighing 115 kg to 137 kg

115	0.23	0.46	0.69	0.92	1.15	1.38	1.61	1.84	2.07	2.30
116	0.23	0.46	0.70	0.93	1.16	1.39	1.62	1.86	2.09	2.32
117	0.23	0.47	0.70	0.94	1.17	1.40	1.64	1.87	2.11	2.34
118	0.24	0.47	0.71	0.94	1.18	1.42	1.65	1.89	2.12	2.36
119	0.24	0.48	0.71	0.95	1.19	1.43	1.67	1.90	2.14	2.38
120	0.24	0.48	0.72	0.96	1.20	1.44	1.68	1.92	2.16	2.40
121	0.24	0.48	0.73	0.97	1.21	1.45	1.69	1.94	2.18	2.42
122	0.24	0.49	0.73	0.98	1.22	1.46	1.71	1.95	2.20	2.44
123	0.25	0.49	0.74	0.98	1.23	1.48	1.72	1.97	2.21	2.46
124	0.25	0.50	0.74	0.99	1.24	1.49	1.74	1.98	2.23	2.48
125	0.25	0.50	0.75	1.00	1.25	1.50	1.75	2.00	2.25	2.50
126	0.25	0.50	0.76	1.01	1.26	1.51	1.76	2.02	2.27	2.52
127	0.25	0.51	0.76	1.02	1.27	1.52	1.78	2.03	2.29	2.54
128	0.26	0.51	0.77	1.02	1.28	1.54	1.79	2.05	2.30	2.56
129	0.26	0.52	0.77	1.03	1.29	1.55	1.81	2.06	2.32	2.58
130	0.26	0.52	0.78	1.04	1.30	1.56	1.82	2.08	2.34	2.60
131	0.26	0.52	0.79	1.05	1.31	1.57	1.83	2.10	2.36	2.62
132	0.26	0.53	0.79	1.06	1.32	1.58	1.85	2.11	2.38	2.64
133	0.27	0.53	0.80	1.06	1.33	1.60	1.86	2.13	2.39	2.66
134	0.27	0.54	0.80	1.07	1.34	1.61	1.88	2.14	2.41	2.68
135	0.27	0.54	0.81	1.08	1.35	1.62	1.89	2.16	2.43	2.70
136	0.27	0.54	0.82	1.09	1.36	1.63	1.90	2.18	2.45	2.72
137	0.27	0.55	0.82	1.10	1.37	1.64	1.92	2.19	2.47	2.74

Patients weighing 138 kg to 150 kg

138	0.28	0.55	0.83	1.10	1.38	1.66	1.93	2.21	2.48	2.76
139	0.28	0.56	0.83	1.11	1.39	1.67	1.95	2.22	2.50	2.78
140	0.28	0.56	0.84	1.12	1.40	1.68	1.96	2.24	2.52	2.80
141	0.28	0.56	0.85	1.13	1.41	1.69	1.97	2.26	2.54	2.82
142	0.28	0.57	0.85	1.14	1.42	1.70	1.99	2.27	2.56	2.84
143	0.29	0.57	0.86	1.14	1.43	1.72	2.00	2.29	2.57	2.86
144	0.29	0.58	0.86	1.15	1.44	1.73	2.02	2.30	2.59	2.88
145	0.29	0.58	0.87	1.16	1.45	1.74	2.03	2.32	2.61	2.90
146	0.29	0.58	0.88	1.17	1.46	1.75	2.04	2.34	2.63	2.92
147	0.29	0.59	0.88	1.18	1.47	1.76	2.06	2.35	2.65	2.94
148	0.30	0.59	0.89	1.18	1.48	1.78	2.07	2.37	2.66	2.96
149	0.30	0.60	0.89	1.19	1.49	1.79	2.09	2.38	2.68	2.98
150	0.30	0.60	0.90	1.20	1.50	1.80	2.10	2.40	2.70	3.00

How to Calculate Nplate® Dose

Volumes to administer for patients weighing 23 kg and above do not require additional dilution

Patients weighing 115 kg to 137 kg

Patient weight (kg)	Dose (mcg/kg)									
	1 mcg/kg	2 mcg/kg	3 mcg/kg	4 mcg/kg	5 mcg/kg	6 mcg/kg	7 mcg/kg	8 mcg/kg	9 mcg/kg	10 mcg/kg
	Total injection volume (mL) required for individual patient dose									

Patients weighing 138 kg to 150 kg

Patient weight (kg)	Dose (mcg/kg)									
	1 mcg/kg	2 mcg/kg	3 mcg/kg	4 mcg/kg	5 mcg/kg	6 mcg/kg	7 mcg/kg	8 mcg/kg	9 mcg/kg	10 mcg/kg
	Total injection volume (mL) required for individual patient dose									

Individual patient dose (mcg) = patient's initial weight (kg) × dose in mcg/kg

$$\text{Injection volume in mL*} = \frac{\text{individual patient dose (mcg)}}{\text{500 mcg/mL}}$$

*Round volume to the nearest hundredth mL

- = One 125 mcg vial
- = One 250 mcg vial
- = One 250 mcg vial + one 125 mcg vial
- = One 500 mcg vial
- = One 500 mcg vial + one 125 mcg vial
- = One 500 mcg vial + one 250 mcg vial
- = One 500 mcg vial + one 250 mcg vial + one 125 mcg vial
- = Two 500 mcg vials
- = Two 500 mcg vials + one 125 mcg vial
- = Two 500 mcg vials + one 250 mcg vial
- = Two 500 mcg vials + one 250 mcg vial + one 125 mcg vial
- = Three 500 mcg vials

Dosing Adjustments

Dose adjustment guidance based on platelet counts:

Platelet count ($\times 10^9$/L)	Action
< 50	Increase once weekly dose by 1 mcg/kg
> 150 for two consecutive weeks	Decrease once weekly dose by 1 mcg/kg
> 250	Do not administer, continue to assess the platelet count weekly After the platelet count has fallen to $< 150 \times 10^9$/L, resume dosing with once weekly dose reduced by 1 mcg/kg

Due to the interindividual variable platelet response, in some patients platelet count may abruptly fall below 50×10^9/L after dose reduction or treatment discontinuation. In these cases, if clinically appropriate, higher cut-off levels of platelet count for dose reduction (200×10^9/L) and treatment interruption (400×10^9/L) may be considered according to medical judgement.

A maximum once weekly dose of 10 mcg/kg should not be exceeded.

Nplate® should continue to be administered weekly unless a platelet count of $> 250 \times 10^9$/L is achieved.

Directions for Dose Reconstitution and Administration

- Nplate® is a highly potent peptide administered subcutaneously as a low-volume dose. Nplate® is supplied as a powder for reconstitution with sterile water for injections.
- Nplate® is approved in three vial sizes. When reconstituted as directed, all vials provide a solution with a concentration of 500 mcg/mL (regardless of the vial size). Because of the holdup in the vial and syringe, the deliverable amount of Nplate® is less than the reconstituted amount.
  - Nplate® 125 micrograms powder for solution for injection should be reconstituted with 0.44 mL sterile water for injections, yielding a deliverable volume of 0.25 mL. An additional overfill is included in each vial to ensure that 125 mcg of romiplostim can be delivered (see vial content table below).
  - Nplate® 250 micrograms powder for solution for injection should be reconstituted with 0.72 mL sterile water for injections, yielding a deliverable volume of 0.50 mL. An additional overfill is included in each vial to ensure that 250 mcg of romiplostim can be delivered (see vial content table below).
  - Nplate® 500 micrograms powder for solution for injection should be reconstituted with 1.20 mL sterile water for injections, yielding a deliverable volume of 1.00 mL. An additional overfill is included in each vial to ensure that 500 mcg of romiplostim can be delivered (see vial content table below).

Vial content:

Nplate® single-use vial	Total vial content of romiplostim		Volume of sterile water for injections		Deliverable product and volume	Final concentration
125 mcg	230 mcg	add	0.44 mL	=	125 mcg in 0.25 mL	500 mcg/mL
250 mcg	375 mcg	add	0.72 mL	=	250 mcg in 0.50 mL	500 mcg/mL
500 mcg	625 mcg	add	1.20 mL	=	500 mcg in 1.00 mL	500 mcg/mL

- Smaller amounts of Nplate® may be required for weekly injection in patients for whom low weekly doses are appropriate, as well as during the titration phase.
- Administer Nplate® as a weekly subcutaneous injection with dose adjustments based on the platelet count response (paediatric and adult patients) and patient's weight (paediatric patients only).
- Injection volume may be very small. Use a syringe with graduations to 0.01 mL.

Prescribing Information

[Prescribing information for Nplate® can be found on the EMA website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000942/human_med_000938.jsp&mid=WC0b01ac058001d124

If available, provide a link to the website of the local competent authority holding Nplate® Product Information. If stipulated by your local regulation, add your local Abbreviated PI or local equivalent as required]

Please report any adverse reactions to the Medicines Authority by post or e-mail:

ADR reporting/ Sir Temi Zammit Building, Malta Life Sciences Park, San Gwann
or on www.medicinesauthority.gov.mt/adrportal