

Revcovi[®] (elapegademase-lvlr) Dosing and Administration Guide

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Ashley, actual Revcovi patient

Indication

Revcovi[®] (elapegademase-lvlr) is indicated for the treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients.

Important Safety Information

Warnings and precautions

- Injection site bleeding in patients with thrombocytopenia: Increased risk of local bleeding in patients with thrombocytopenia; should not be used if thrombocytopenia is severe.
- Delay in improvement of immune function: Protect immune deficient patients from infections until improvement in immune function.

Adverse reactions

The most commonly reported adverse reactions were cough (50%) and vomiting (33%).

In addition, the following post-marketing reports for the same class of enzyme replacement therapy used in the treatment of ADA-SCID may also be seen with Revcovi treatment:

- Hematologic events: hemolytic anemia, autoimmune hemolytic anemia, thrombocythemia, thrombocytopenia and autoimmune thrombocytopenia
- · Dermatological events: injection site erythema, urticaria
- Lymphomas

Important monitoring information

Treatment with Revcovi should be monitored by measuring trough plasma ADA activity and trough dAXP levels for maintenance of therapeutic targets. If a persistent decline in plasma ADA activity occurs, immune function and clinical status should be monitored closely, and precautions should be taken to minimize the risk of infection.

Please see accompanying Prescribing Information.



Individualized treatment for your patients with ADA-SCID¹

Meet each patient's unique needs with individualized dosing and careful lab monitoring.¹

Therapeutic monitoring helps achieve appropriate dosing¹

Recommended starting dose¹



0.4 mg/kg/wk based on ideal body weight or actual weight, whichever is greater



Divided into 2 weekly doses for a minimum of 12-24 weeks



Until immune reconstitution is achieved

- Once immune reconstitution is achieved, dose may be gradually adjusted down to maintain trough ADA activity >30 mmol/hr/L, trough dAXP levels <0.02 mmol/L, and/or to maintain adequate immune reconstitution based on the clinical assessment of the patient¹
- Improvement in the general clinical status of the patient may be gradual but should be apparent by the end of the first year of therapy¹

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Please see additional Important Safety Information throughout and accompanying full Prescribing Information.

Monitoring schedule¹

	First 3 months	4-12 months	1 year+ of
	of treatment:	of treatment:	treatment:
	monitor patients	monitor patients	monitor patients
	every 2 weeks	every 1-2 months	every 3-6 months
ADA Activity Target trough plasma ADA activity ≥30 mmol/h/Lª	Every 2 weeks	Every 3-6 months	Every 3-6 months
Erythrocyte dAXP	At week 8	Every	Every
Target trough dAXP levels <0.02 mmol/L		6 months	6 months
Total & Subset Lymphocytes	At weeks	Every	Every
Target general improvement ^b	4, 8, and 12	1-2 months	3-6 months



a A decrease of ADA activity below 30 mmol/hr/L might suggest noncompliance or a development of antibodies (anti-drug, anti-PEG, and neutralizing antibodies). Test for antibodies to Revcovi if pre-injection trough plasma ADA activity falls below 15 mmol/hr/L consistently. If there is a decline in ADA activity levels, monitor immune function and clinical status more closely and take precautions to minimize the risk of infection.¹

b Immune function, including the ability to produce antibodies, generally improves after 2-6 months of therapy, and matures over a longer period. Improvement in the general clinical status of the patient may be gradual (as evidenced by improvement in various clinical parameters) but should be apparent by the end of the first year of therapy.¹



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Chiesi Total Care^{s™} is a comprehensive support program that provides exceptional service to patients and healthcare providers.

A single call to your dedicated Chiesi Total Care team is all it takes, and they will guide you through the process of getting a patient started on Revcovi therapy.

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Please see full Prescribing Information inside.

References: 1. Revcovi® (elapegademase-lvlr) Prescribing Information. Chiesi USA, Inc.; 2020.

