

# ELTROMBOPAG

November 2011

## **Note**

Eltrombopag is not PBS subsidised as an alternative to splenectomy.

Any queries concerning the arrangements to prescribe eltrombopag may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe eltrombopag should be forwarded to:

Medicare Australia  
Prior Written Approval of Specialised Drugs  
Reply Paid 9826  
GPO Box 9826  
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)

## **Authority required**

Initial (new patients)

Initial treatment, as the sole PBS subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who is:

(1) Splenectomised and:

- (a) has had an inadequate response to, or is intolerant to, corticosteroid therapy post splenectomy; and
- (b) has had an inadequate response to, or is intolerant to, immunoglobulin therapy post splenectomy;

OR

(2) Not splenectomised and:

- (a) has had an inadequate response, or is intolerant to, corticosteroid therapy at a dose equivalent to 0.5-2 mg/kg/day of prednisone for at least 4-6 weeks; and
- (b) has had an inadequate response, or is intolerant to, immunoglobulin therapy; and
- (c) in whom splenectomy is contraindicated for medical reasons.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of initial application:

(a) a platelet count of less than or equal to 20,000 million per L;

OR

(b) a platelet count of 20 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,

- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))],
- (4) a copy of a full blood count pathology report supporting the diagnosis of ITP, and
- (5) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

The full blood count must be no more than 1 month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

**Note**

Patients will be able to trial either eltrombopag and/or romiplostim within the initial 24 weeks treatment period. Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS subsidised treatment with either of these drugs.

No applications for increased repeats will be authorised.

**Authority required**

Initial (grandfather patients)

Initial treatment, as the sole PBS subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with severe chronic immune (idiopathic) thrombocytopenic purpura (ITP) who was receiving treatment with eltrombopag prior to 1 November 2011 and in whom the criteria for initial treatment can be demonstrated to have been met at the time eltrombopag was commenced.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form,
- (2) a signed patient acknowledgement,
- (3) a completed Idiopathic Thrombocytopenic Purpura Initial PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))],
- and (4) where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

**Note**

No applications for increased repeats will be authorised.

**Authority required**

Continuing therapy or re initiation after a break in therapy  
First period of PBS subsidised continuing treatment or re initiation of interrupted PBS subsidised treatment, as the sole PBS subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has displayed a sustained platelet response to treatment with eltrombopag during the initial period of PBS subsidised treatment.

For the purposes of this restriction, a sustained platelet response is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the initial period of PBS subsidised eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L on at least four (4) occasions, each at least one week apart;

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline (pre treatment) platelet count on at least four (4) occasions, each at least one week apart.

Applications for the first period of continuing PBS subsidised treatment or re initiation of interrupted treatment must be made in writing and must include:

(1) a completed authority prescription form, and

(2) a completed Idiopathic Thrombocytopenic Purpura Continuing PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)) ], and

(3) copies of the platelet count pathology reports (unless previously provided for patients re initiating therapy).

The most recent platelet count must be no more than one month old at the time of application.

A maximum of 24 weeks of treatment with eltrombopag will be authorised under this criterion.

Where fewer than 5 repeats are initially requested with the authority prescription, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be made by telephone.

**Note**

No applications for increased repeats will be authorised.

**Authority required**

Second and subsequent applications for continuing therapy  
Continuing treatment, as the sole PBS subsidised thrombopoietin receptor agonist (TRA), of severe thrombocytopenia in an adult patient with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who has previously

received PBS subsidised therapy with eltrombopag and who continues to display a response to treatment with eltrombopag.

For the purposes of this restriction, a continuing response to treatment with eltrombopag is defined as:

(a) use of rescue medication (corticosteroids or immunoglobulins) on no more than one occasion during the most recent 24 week period of PBS subsidised treatment with eltrombopag,

AND either of the following:

(b) a platelet count greater than or equal to 50,000 million per L

OR

(c) a platelet count greater than 30,000 million per L and which is double the baseline platelet count.

Platelet counts must be no more than 1 month old at the time of application.

Authority applications for second and subsequent periods of continuing therapy may be made by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Note**

No applications for increased repeats will be authorised.

**5825N**

**Tablet 25mg**

**Revolade**

**5826P**

**Tablet 50mg**

**Revolade**