MERIDIAN THERAPEUTICS

Emrelimab

FULL PRESCRIBING INFORMATION · United States

This document is fictional and is provided for demonstration purposes only.
It is not real prescribing information and must not be used to inform clinical decisions.
Intended for healthcare professionals.

1. INDICATION

EMRELIMAB (emrelimab) injection is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Limitations of Use: The safety and effectiveness of EMRELIMAB in patients with other forms of psoriasis have not been established.

2. DOSAGE AND ADMINISTRATION

The recommended dose is 300 mg administered by subcutaneous injection at weeks 0, 4, and every 12 weeks thereafter.

Each 300 mg dose is given as two subcutaneous injections of 150 mg. Injection sites should be rotated and the product should not be injected into skin that is tender, bruised, erythematous, indurated, or affected by psoriasis.

Patients should complete all age-appropriate immunizations before initiating therapy.

3. IMPORTANT SAFETY INFORMATION

EMRELIMAB is contraindicated in patients with a history of serious hypersensitivity reaction to emrelimab or to any of the excipients.

EMRELIMAB may increase the risk of infection. Treatment should not be initiated in patients with a clinically important active infection. Patients should be evaluated for tuberculosis infection prior to initiating treatment, and monitored for signs and symptoms of active tuberculosis during and after treatment.

Cases of anaphylaxis and angioedema have been reported. If a serious hypersensitivity reaction occurs, administration should be discontinued immediately and appropriate therapy initiated.

The most commonly reported adverse reactions, occurring in at least 1% of patients, were upper respiratory tract infections, headache, injection site reactions, and arthralgia.

This is not a complete summary of the safety information for EMRELIMAB. Please consult the full Prescribing Information.

4. REPORTING OF SUSPECTED ADVERSE REACTIONS

To report a suspected adverse reaction, contact Meridian Therapeutics Drug Safety on 1-800-555-0142 or safety.us@meridiantx.example. You are also encouraged to report suspected adverse reactions to your national regulatory authority.

5. APPROVAL RECORD

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