Safety Alert

Jan 2025

Teriflunomide – Risk of herpes virus infections

EDA performs label update to include the following:

Special warnings and precautions for use

Infections

Cases of herpes virus infections, including oral herpes and herpes zoster, have been reported with teriflunomide, with some of them being serious, including herpetic meningoencephalitis and herpes Cases of herpes virus infections, including oral herpes and herpes zoster, have been reported with teriflunomide, with some of them being serious, including herpetic meningoencephalitis and herpes dissemination. They may occur at any time during treatment.

Undesirable effects

Infections and Infestations

Common: Herpes infection

Background:

Theraputic Indication

Teriflunomide is indicated for the treatment of patients with relapsing forms of Multiple Sclerosis (MS) to reduce the frequency of clinical relapses and to delay the progression of physical disability.

Herpes infection

- Herpes infections are categorized by the area of the body that is infected. The two major types of herpes are oral herpes and genital herpes, though other forms also exist.
- Oral herpes involves the face or mouth. It may result in small blisters in groups, often called cold sores or fever blisters, or may just cause a sore throat.
- Genital herpes involves the genitalia. It may have minimal symptoms or form blisters that break open and result in small ulcers. These typically heal over two to four weeks. Tingling or shooting pains may occur before the blisters appear

<u>References:</u> EMA <u>(Click here)</u>