אוגוסט 2022

Lemtrada

Concentrate for Solution for Infusion

חומר פעיל: Alemtuzumab 12mg/1.2mL

ההתוויה המאושרת:

LEMTRADA is indicated as a single disease modifying therapy in adults with highly active relapsing remitting multiple sclerosis (RRMS) for the following patient groups:

- Patients with highly active disease despite a full and adequate course of treatment with at least one disease modifying therapy (DMT) or
- Patients with rapidly evolving severe relapsing remitting multiple sclerosis defined by 2 or more disabling relapses in one year, and with 1 or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI.

חברת סאנופי אוונטיס מבקשת להודיע על עדכון העלון לצרכן במתכונת עלון לרופא ביולי 2022.

העדכונים העיקריים הם:

4.4 Special warnings and precautions for use

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Traceability
In order to improve the traceability of biological medicinal products, the name of the administered product should be clearly recorded. It is recommended to record the batch number as well.

Autoimmunity

Treatment may result in the formation of autoantibodies and increase the risk of autoimmune mediated conditions which may be serious and life threatening. Reported autoimmune conditions, include thyroid disorders, immune thrombocytopenic purpura (ITP), nephropathies (e.g. anti-glomerular basement membrane disease), autoimmune hepatitis (AIH), acquired haemophilia A, thrombotic thrombocytopenic purpura, ~~and~~ sarcoidosis, and autoimmune encephalitis. In the post-marketing setting, patients developing multiple autoimmune disorders after LEMTRADA treatment have been observed. Patients who develop autoimmunity should be assessed for other autoimmune mediated conditions (see section 4.3). Patients and physicians should be made aware of the potential later onset of autoimmune disorders after the 48 months monitoring period.

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Autoimmune Encephalitis
Cases of autoimmune encephalitis have been reported in patients treated with LEMTRADA. Autoimmune encephalitis is characterized by subacute onset (with rapid progression over months) of memory impairment, altered mental status or psychiatric symptoms, generally in combination with new onset focal neurological findings and seizures. Patients with suspected autoimmune encephalitis should have neuroimaging (MRI), EEG, lumbar puncture and serologic testing for appropriate biomarkers (e.g. neural autoantibodies) to confirm diagnosis and exclude alternative etiologies.

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4.8 Undesirable effects

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System Organ Class	Very Common	Common	Uncommon	Rare	Not known
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Nervous system disorders	…..	…..	Sensory disturbance, hyperaesthesia, tension headache, autoimmune encephalitis		…..
…..	…..	…..	…..	…..	…..
Skin and subcutaneous tissue disorders	…..	…..	Blister, night sweats, swelling face, eczema, vitiligo		
…..	…..	…..	…..	…..	…..

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העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום - סאנופי-אוונטיס ישראל בע"מ, רח' בני גאון 10 נתניה או בטלפון: 09-8633700 .

להלן הקישור לאתר משרד הבריאות: https://israeldrugs.health.gov.il/#!/byDrug

בברכה,
חברת סאנופי-אוונטיס ישראל בע"מ