ספטמבר, 2021

Lemtrada

Concentrate for Solution for Infusion

חומר פעיל: Alemtuzumab 12mg/1.2mL

ההתוויה המאושרת:

LEMTRADA is indicated for adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease defined by clinical or imaging features

חברת סאנופי אוונטיס מבקשת להודיע על עדכון העלון לצרכן במתכונת עלון לרופא באוגוסט 2021.

העדכונים העיקריים הם:

4.4 Special warnings and precautions for use

…..

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), ~~and~~ acquired haemophilia A, and thrombotic thrombocytopenicpurpura. 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.

…..

Thrombotic Thrombocytopenic Purpura (TTP)

Development of TTP has been reported in patients treated with LEMTRADA during post-marketing use, including a fatal case. TTP is a serious condition that requires urgent evaluation and prompt treatment, and can develop several months after last LEMTRADA infusion. TTP may be characterized by thrombocytopenia, microangiopathic hemolytic anemia, neurological symptoms, fever and renal impairment.

…..

סאנופי אוונטיס ישראל, רח' בני גאון 10, פארק פולג, ת.ד. 8090, נתניה דרום 42504
טל': 09-8633700 פקס: 09-8851444

4.8 Undesirable effects

…..

System Organ Class	Very Common	Common	Uncommon	Rare	Not known
…..	…..	…..	…..	…..	…..
Blood and lymphatic system disorders	Lymphopenia, leukopenia, including neutropenia	Lymphadenopathy, immune thrombocytopenic purpura, thrombocytopenia, anaemia, haematocrit decreased, leukocytosis	Pancytopenia, haemolytic anaemia, acquired haemophilia A	Haemophagocytic lymphohistiocytosis (HLH), thrombotic thrombocytopenic purpura (TTP)	
…..	…..	…..	…..	…..	…..

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://data.health.gov.il/drugs/index.html#/byDrug

בברכה,

גליה הוכשטד
רוקחת ממונה