אוקטובר, 2021

Lemtrada concentrate for Solution for Infusion

חומר פעיל: Alemtuzumab 12mg/1.2mL

חברת סאנופי אוונטיס מבקשת להודיע על **עדכון התווית התכשיר והעלון לרופא** באוקטובר 2021.

להלן נוסח ההתוויה העדכנית 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.

בנוסף להתוויה, העדכונים העיקריים בעלון הם בסעיפים הבאים:

4.2 Posology and method of administration

LEMTRADA treatment should only be initiated and supervised by a neurologist experienced in the treatment of patients with ~~MS~~ multiple sclerosis (MS) in a hospital with ready access to intensive care. Specialists and equipment required for the timely diagnosis and management of ~~the most frequent~~ adverse reactions, especially myocardial ischaemia and myocardial infarction, cerebrovascular adverse reactions, autoimmune conditions and infections, should be available.

Resources for the management of cytokine release syndrome, hypersensitivity and/or anaphylactic reactions should be available.

Patients treated with LEMTRADA must be given the Patient Alert Card and Patient Guide and be informed about the risks of LEMTRADA.

Posology

The recommended dose of alemtuzumab is 12 mg/day administered by intravenous infusion for 2 initial treatment courses, with up to 2 additional treatment courses if needed.

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Initial treatment of 2 courses:

- First treatment course: 12 mg/day on 5 consecutive days (60 mg total dose).
- Second treatment course: 12 mg/day on 3 consecutive days (36 mg total dose) administered 12 months after the first treatment course.

Up to two additional treatment courses, as needed, may be considered (see section 5.1):

• Third or fourth course: 12 mg/day on 3 consecutive days (36 mg total dose) administered at least 12 months after the prior treatment course ~~in patients with MS disease activity defined by clinical or imaging features~~ (see section 4.1, 5.1).

Missed doses should not be given on the same day as a scheduled dose.

Follow-up of patients

The therapy is recommended as an initial treatment of 2 courses with up to 2 additional treatment courses if needed (see posology) with safety follow-up of patients from initiation of the first treatment course and for at least ~~until~~ 48 months after the last infusion of the second treatment course. If an additional third or fourth course is administered, continue safety follow-up for at least ~~until~~ 48 months after the last infusion (see section 4.4).

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השינוי ל: for at least ~~until~~ 48 months מופיע גם בסעיפים נוספים בעלון.

4.4 Special warnings and precautions for use

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Infusion instructions to reduce serious reactions temporally associated with LEMTRADA infusion

• Pre-infusion evaluations:
  - o Obtain a baseline ECG and vital signs, including heart rate and blood pressure measurement.
  - o Perform laboratory tests (complete blood count with differential, serum transaminases, serum creatinine, test of thyroid function and urinanalysis with microscopy).

• During infusion:
  - o Perform continuous/frequent (at least every hour) monitoring of heart rate, blood pressure and overall clinical status of the patients
    - ▪ Discontinue the infusion
      - • In case of a severe adverse event
      - • If the patient shows clinical symptoms suggesting development of a serious adverse event associated with the infusion (myocardial ischemia, hemorrhagic stroke, cervico-cephalic arterial dissection or pulmonary alveolar haemorrhage

• Post-infusion:
  - o Observation for infusion reactions is recommended for a minimum of 2 hours after LEMTRADA infusion. Patients with clinical symptoms suggesting development of a serious adverse event

temporally associated with the infusion (myocardial ischemia, haemorrhagic stroke, cervico-cephalic arterial dissection or pulmonary alveolar haemorrhage) should be closely monitored until complete resolution of the symptoms. The observation time should be extended (hospitalisation) as appropriate. The patients should be educated on the potential for delayed onset of infusion associated reactions and instructed to report symptoms and seek appropriate medical care.

o Platelet count should be obtained immediately after infusion on Days 3 and 5 of the first infusion course, as well as immediately after infusion on Day 3 of any subsequent course. Clinically significant thrombocytopenia needs to be followed until resolution. Referral to a haematologist for management should be considered.

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התוכנית לניהול סיכונים הקיימת לתכשיר תעודכן לגבי האמצעים למזעור סיכונים.

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