נובמבר 2020

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 בנובמבר 2020.

העדכונים העיקרים הינם:

4.4. Special warnings and precautions for use

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Pericarditis

Rare cases of pericarditis, pericardial effusion and other pericardial events have been reported, both as part of acute infusion reaction and with later onset.

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Progressive Multifocal Leukoencephalopathy (PML)

Rare cases of PML (including fatal), have been reported in MS patients after treatment with alemtuzumab. Patients treated with alemtuzumab must be monitored for any signs that may be suggestive of PML. Risk factors of special importance include previous immunosuppressive treatment, in particular other MS treatments with known risk of causing PML.

MRI findings may be apparent before clinical signs or symptoms. Prior to initiation and readministration of alemtuzumab treatment, MRI scan should be made and evaluated for signs that are consistent with PML. Further evaluation, including cerebrospinal fluid (CSF) testing for JC Viral DNA and repeat neurological assessments should be performed as appropriate. The physician should be particularly alert to symptoms suggestive of

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PML that the patient may not notice (e.g. cognitive, neurological or psychiatric symptoms). Patients should also be advised to inform their relatives or caregivers about their treatment, since they may notice symptoms that the patient is not aware of. PML should be considered as a differential diagnosis in any MS patient taking alemtuzumab presenting with neurological symptoms and/or new brain lesions in MRI.

If a diagnosis of PML has been made, treatment with alemtuzumab should not be started or restarted.

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Infections and infestations
Serious and sometimes fatal viral, bacterial, protozoan, and fungal infections, including those due to reactivation of latent infections, have been reported in non-MS patients treated with alemtuzumab at higher and more frequent doses than used in MS.
~~Progressive multifocal leukoencephalopathy (PML) has been reported in patients with B-CLL with or without treatment with alemtuzumab. The frequency of PML in B-CLL patients treated with alemtuzumab is no greater than the background frequency.~~

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,

אסנת מירון - עוזרי
רוקחת ממונה