

26.04.2021

רופא/ה רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכון בעלון לרופא

Ribomustin 25mg
Ribomustin100mg

חומר פעיל :

One vial of Ribomustin 25 mg contains: 25 mg of powder for concentrate for solution for infusion of bendamustine hydrochloride.

One vial of Ribomustin 100 mg contains: 100 mg of powder for concentrate for solution for infusion of bendamustine hydrochloride.

להלן עדכונים בעלון לרופא (טקסט מסומן ירוק משמעותו עדכון, טקסט מסומן צהוב משמעותו החמרה):

[...]

4. CLINICAL PARTICULARS

4.4 Special warnings and precautions for use

[...]

Infections

Serious and fatal infections have occurred with bendamustine hydrochloride, including bacterial (sepsis, pneumonia) and opportunistic infections such as *Pneumocystis jirovecii* pneumonia (PJP), varicella zoster virus (VZV) and cytomegalovirus (CMV). **Cases of progressive multifocal leukoencephalopathy (PML) including fatal ones have been reported following the use of bendamustine mainly in combination with rituximab or obinutuzumab.** Treatment with bendamustine hydrochloride may cause prolonged lymphocytopenia ($< 600/\mu\text{l}$) and low CD4-positive T-cell (T-helper cell) counts ($< 200/\mu\text{l}$) for at least 7–9 months after the completion of treatment. Lymphocytopenia and CD4-positive T-cell depletion are more pronounced when bendamustine is combined with rituximab. Patients with lymphopenia and low CD4-positive T-cell count following treatment with bendamustine hydrochloride are more susceptible to (opportunistic) infections. In case of low CD4-positive T-cell counts ($< 200/\mu\text{l}$) *Pneumocystis jirovecii* pneumonia (PJP) prophylaxis should be considered. All patients should be monitored for respiratory signs and symptoms throughout treatment. Patients should be advised to report new signs of infection, including fever or respiratory symptoms promptly. Discontinuation of bendamustine hydrochloride should be considered if there are signs of (opportunistic) infections. **Consider PML in the differential diagnosis in patients with new or worsening neurological, cognitive or behavioural signs or symptoms. If PML is suspected then appropriate diagnostic evaluations should be undertaken and treatment suspended until PML is excluded.**

[...]

Non-melanoma skin cancer

In clinical studies, an increased risk for non-melanoma skin cancers (basal cell carcinoma and squamous cell carcinoma) has been observed in patients treated with bendamustine containing therapies. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

[...]

העלון לרופא נשלח למאגר התרופות שבאתר משרד הבריאות www.health.gov.il לצורך העלאתו לאתר וניתן לקבלו מודפס על ידי פניה לבעל הרישום אסטלס פארמה אינטרנשונל ביו,י, ת.ד. 11458, ראש העין.

ברכה
גל פרידמן
רוקח ממונה