אוקטובר 2024

Lunsumio® 1 mg/1ml
mosunetuzumab
Concentrate for solution for infusion

רופא/ה יקר/ה, רוקח/ת יקר/ה,

חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשיר לאנסומיו.
בהודעה זו מצוינים רק עדכונים מהותיים ועדכונים אשר מהווים החמרה.

ההתוויות הרשומות לתכשיר בישראל:

Lunsumio as monotherapy is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least two prior systemic therapies.

הסבר:

טקסט עם קו תחתי בצבע כחול מציין טקסט שהוסף לעלון.
~~טקסט עם קו חוצה~~ מציין טקסט שהוסר מן העלון.

למידע נוסף יש לעיין בעלון לרופא כפי שאושר ע"י משרד הבריאות.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על-ידי פנייה לבעל הרישום: רוש פרמצבטיקה (ישראל) בע"מ, ת.ד 6391 , הוד השרון 4524079 טלפון 09-9737777. כתובתנו באינטרנט: www.roche.co.il.

ב ב ר כ ה,

בתאור צפרי-חגג
מחלקת רישום

לילי אדר
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4.2 Posology and method of administration

Lunsumio must only be administered under the supervision of a healthcare professional qualified in the use of anti-cancer therapies, in a setting with appropriate medical support to manage severe reactions such as cytokine release syndrome (CRS) and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) (see section 4.4).

4.4 Special warnings and precautions for use

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

ICANS have occurred in patients receiving Lunsumio, including serious and life threatening reactions. The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Manifestations of ICANS reported in clinical trials included confusional state, lethargy, encephalopathy, depressed level of consciousness, and memory impairment. The majority of cases occurred during Cycle 1.
Patients should be monitored for signs and symptoms of ICANS following Lunsumio administration. Patients must be counselled to seek immediate medical attention should signs or symptoms occur at any time.
Patients should be advised to exercise caution while (or avoid if symptomatic) driving, cycling or using heavy or potentially dangerous machines (see section 4.7).

4.7 Effects on ability to drive and use machines

Lunsumio has ~~minor~~ major influence on the ability to drive and use machines. Due to the potential for ICANS, patients receiving Lunsumio are at risk of depressed level of consciousness (see section 4.4). Due to the potential for ICANS, patients should be advised to exercise caution while (or avoid if symptomatic) driving, cycling or using ~~Patients who experience events that impair consciousness should be evaluated and advised not to drive and to refrain from operating~~ heavy or potentially dangerous machines ~~until events are resolved.~~.

4.8 Undesirable effects

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Table 4 Adverse reactions occurring in patients treated with Lunsumio

System organ class / preferred term or adverse reaction	All grades	Grade 3 – 4
…		
Nervous system disorders		
…		
Immune effector cell-associated neurotoxicity syndrome[4,5]	Common	Very rare

…

[4] Consistent with the medical concept of ICANS according to American Society for Transplant and Cellular Therapy and includes confusional state, ICANS, lethargy, encephalopathy, depressed level of consciousness, and memory impairment

Description of selected adverse reactions

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Immune Effector Cell-Associated Neurotoxicity Syndrome

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) occurred in 2.1% (20/949) of patients, 19 patients had Grade 1-2 events and 1 patient had Grade 3 event. The majority of events occurred during the first cycle of treatment. The majority of cases resolved. The median time to onset from initial dose was 17 days (range: 1 to 48 days). The median duration was 3 days (range: 1-20 days).