ינואר 2025

Columvi® 1 mg/1 mL
glofitamab
Concentrate for Solution for Infusion

רופא/ה יקר/ה, רוקח/ת יקר/ה,
חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על מספר עדכונים שבוצעו בעלון לרופא של התכשיר Columvi.

בהודעה זו מצוינים רק עדכונים מהותיים ועדכונים אשר מהווים החמרה.

ההתוויה הרשומה לתכשיר בישראל:

Columvi is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B cell lymphoma after two or more lines of systemic therapy.

הסבר:

טקסט עם קו תחתי מציין טקסט שהוסף לעלון.
טקסט עם קו תחתי הצבוע בצהוב מציין החמרה.
~~טקסט עם קו חוצה~~ מציין טקסט שהוסר מן העלון.

למידע נוסף יש לעיין בעלון לרופא כפי שנשלחו למשרד הבריאות.

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים 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,

Signed by:
Lily Adar
Signer Name: Lily Adar
Signing Reason: I approve this document
Signing Time: 13-Jan-2025 | 10:10:15 AM CET
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לילי אדר
רוקחת ממונה

Signed by:
Avital Weisbrot
Signer Name: Avital Weisbrot
Signing Reason: I approve this document
Signing Time: 08-Jan-2025 | 10:19:23 AM CET
1EB311AC73A14811A6C1DBA417B19607

אביטל ויסברוט
מחלקת רישום

Roche Pharmaceuticals (Israel) Ltd
Drugs regulatory affairs
6 Hacharash St.
P.O.B. 6391
Hod Hasharon 4524079
Tel. + 972-9-9737777
Fax + 972-9-9737850

עדכונים מהותיים בעלון לרופא

בסעיף 4.4 Special warnings and precautions for use עודכן המידע הבא:

[…]

Immune effector cell-associated neurotoxicity syndrome

Serious cases of immune effector cell-associated neurotoxicity syndrome (ICANS) which could be life-threatening or fatal have occurred following treatment with Columvi (see section 4.8).

The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS. Clinical signs and symptoms of ICANS may include but are not limited to confusion, depressed level of consciousness, disorientation, seizure, aphasia, and dysgraphia.

Patients should be monitored for signs and symptoms of ICANS following Columvi administration and treated promptly. Patients must be counselled to seek immediate medical attention should signs or symptoms occur at any time (*see Patient card*).

At the first signs or symptoms of ICANS, manage according to the ICANS guidance provided in Table 4. Treatment with Columvi should be withheld or discontinued permanently as recommended.

בסעיף 4.7 Effects on ability to drive and use machines עודכן המידע הבא:

Columvi has ~~minor~~ major influence on the ability to drive and use machines .
~~Patients experiencing symptoms of neurological adverse events and/or CRS (pyrexia, tachycardia, hypotension, chills, hypoxia) should be advised not to drive or use machines until symptoms resolve (see sections 4.4 and 4.8).~~

Due to the potential for ICANS, patients receiving Columvi are at risk of depressed level of consciousness (see section 4.4). Patients should be instructed to avoid driving or operating machines for 48 hours after each of the first two doses during the step-up dosing and in the event of new onset of any symptoms of ICANS (confusion, disorientation, depressed level of consciousness) and/or CRS (pyrexia, tachycardia, hypotension, chills, hypoxia) until symptoms resolve (see sections 4.4 and 4.8).

בסעיף 4.8 Undesirable Effects עודכן המידע הבא:

Table 5. Adverse reactions reported in patients with relapsed or refractory DLBCL treated with Columvi monotherapy

System organ class	Adverse reaction	All grades	Grade 3–4
Nervous system disorders	Headache	Very common	Very rare**
	Immune effector cell-associated neurotoxicity syndrome[10]	Common	Uncommon
	Somnolence	Common	Uncommon
	Tremor	Common	Very rare**
	Myelitis[11]	Uncommon	Uncommon

* Grade 5 reactions reported. See serious infections in *Description of selected adverse reactions.*

** No Grade 3-4 events were reported.

[…]

[10] ICANS based on Lee 2019 and includes somnolence, cognitive disorder, confusional state, delirium, and disorientation.

[11] Myelitis occurred concurrently with CRS.

[…]

Description of selected adverse reactions

~~Neurologic Toxicity~~
~~Among 145 patients who received Columvi, the most frequent neurologic toxicities of any grade were headache (10%), peripheral neuropathy (8%), dizziness or vertigo (7%), and mental status changes (4.8%, including confusional state, cognitive disorder, disorientation, somnolence, and delirium). Grade 3 or higher neurologic adverse reactions occurred in 2.1% of patients and included somnolence, delirium, and myelitis. Cases of ICANS of any grade occurred in 4.8% of patients .~~

[…]

Immune effector cell-associated neurotoxicity syndrome
ICANS, including Grade 3 and higher, was reported in clinical trials and with post-marketing experience. The most frequent clinical manifestations of ICANS were confusion, depressed level of consciousness, disorientation, seizure, aphasia, and dysgraphia. Based on the available data, the onset of neurologic toxicity was concurrent with CRS in the majority of cases.

The observed time to onset of the majority of ICANS was 1-7 days with median of 2 days after the most recent dose. Only few events were reported to have occurred more than one month after the initiation of Columvi.