Important Safety Information for Patients Receiving Columvi® (glofitamab) 1 mg /1 mL

Patient Card

- Please carry this card with you at all times while you are receiving Columvi.
- Show this card to any healthcare professionals involved in your care.

Information for the patient

Contact your Doctor or get emergency help **right away** if you have any of these symptoms:

Cytokine Release Syndrome (CRS)

- Fever (38°C or higher)
- Fast heartbeat
- Chills
- Shortness of breath
- Feeling dizzy or lightheaded

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

- Confusion
- Cognitive disorder
- Disorientation
- Drowsiness
- Delirium
- Decreased consciousness
- Seizures
- Difficulty speaking or writing
- Memory loss
- Muscle weakness

Experiencing any of these symptoms could be due to **Cytokine Release Syndrome** or **Immune Effector Cell-Associated Neurotoxicity Syndrome**, which requires immediate evaluation by a Doctor.

Cytokine Release Syndrome (CRS)

- is a group of symptoms caused by small proteins called cytokines, released in your body during inflammation.
- may be caused by receiving Columvi.

Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

- is a group of symptoms caused by impaired function of the nervous system.
- may be caused by receiving Columvi.

Information for healthcare professionals

This patient has received Columvi - **which may cause Cytokine Release Syndrome (CRS) and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).**

- Evaluate the patient immediately and treat symptoms.
- If CRS or ICANS is suspected, refer to sections 4.2 and 4.4 in the prescribing information for detailed information about how to treat these syndromes.
- **Contact the treating hematologist** when possible - he may need to modify the next infusion of Columvi.

Contact information

Patient's name:

Treating hematologist's name:

Treating hematologist's phone number:

Date of Columvi initiation:

Reporting adverse events

If you experience any side effects, contact your doctor as soon as possible.

Side effects can be reported to the Ministry of Health, using the online form for reporting side effects on the Ministry of Health homepage www.health.gov.il or using the link: https://sideeffects.health.gov.il/, or to Roche at email address Israel.DrugSafety@roche.com

Reporting side effects can provide additional information about the safety of this medicine.

For more information about safety, speak with your doctor.

For complete information about Columvi, please refer to the drug leaflet on the Ministry of Health's website at https://israeldrugs.health.gov.il/#!/byDrug or on the Roche website at www.roche.co.il

For more information, contact the company:
Roche Pharmaceuticals (Israel) Ltd.
6 HaHarash St.,
PO Box 6391, Hod Hasharon 4524079
Telephone: 09-9737777
www.roche.co.il

The format and content of this patient card were approved by the Ministry of Health in December 2024.

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