

## Contact Information for Healthcare Professionals

Please contact the patient's haematologist (details overleaf) for more information.

Please consult the Summary of Product Characteristics for Columvi (glofitamab) available at: [www.medicines.org.uk](http://www.medicines.org.uk); or contact Roche Medical Information (tel: 0800 328 1629, email: [medinfo.uk@roche.com](mailto:medinfo.uk@roche.com)).

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

## Important Information for Patients

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

Please report suspected side effects to the MHRA through the Yellow Card scheme, via the Yellow Card website [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard), or the free Yellow Card app available in the [Apple App Store](#) or [Google Play Store](#). Alternatively you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

Side effects should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing [welwyn.uk\\_dsc@roche.com](mailto:welwyn.uk_dsc@roche.com) or calling +44 (0)1707 367554. By reporting suspected side effects, you can help provide more information on the safety of this medicine.

Date of Columvi initiation:

Name of haematologist:

Contact Number:

After-hours contact number:

My name:

My contact number:

Emergency contact:

Emergency contact number:



## Important Safety Information for Patients Receiving Columvi®▼(glofitamab): Patient Card

Columvi is used to treat patients for the following indications:

- Columvi as monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy;
- Columvi in combination with gemcitabine and oxaliplatin is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma not otherwise specified (DLBCL NOS) who are ineligible for autologous stem cell transplant (ASCT).

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Please carry this card with you at all times while you are receiving Columvi (glofitamab).

Show this card to ALL Healthcare Professionals (including doctors, nurses, pharmacists) involved in your treatment and at any visits to the hospital.

This educational material is provided by Roche Products Limited and is mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks.

## Important Information for the Patient

**Contact your Doctor or get emergency help right away if you have any of these symptoms. Do not attempt to diagnose and treat these symptoms yourself.**

- Fever (38°C or higher)
- Fast heartbeat
- Chills
- Confusion
- Shortness of breath
- Dizziness or lightheadedness
- Headache
- Nausea
- Sleepiness
- Change in consciousness level
- Having difficulty writing and/or speaking
- Rash
- Feeling disorientated
- Feeling less alert

**Tell your doctor if these symptoms persist or worsen.**

Experiencing any of these symptoms could be due to **Cytokine Release Syndrome and/or neurotoxicity symptoms**, 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 involve any organ systems.
- may be caused by receiving Columvi.

### Immune effector cell-associated neurotoxicity syndrome (ICANS):

- is a condition that affects the brain and nervous system caused by an overactive immune system.
- may be caused by receiving Columvi and can range in severity from mild to severe.
- has an onset which can either be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

Please refer to the Patient Information Leaflet (PIL) for Columvi (glofitamab) for more information, which is available at: [www.medicines.org.uk](http://www.medicines.org.uk).

## Important Information for Healthcare Professionals

This patient has received Columvi (glofitamab) - which may cause **Cytokine Release Syndrome (CRS) and/or Immune effector cell-associated neurotoxicity syndrome (ICANS)**.

- Evaluate the patient immediately for signs and symptoms of CRS and/or ICANS and treat symptoms accordingly.
- CRS may involve any organ systems and can be serious and life-threatening.
- If CRS and/or ICANS is suspected, please refer to the latest product information for Columvi (glofitamab) for comprehensive instructions on CRS and ICANS management.
- **Contact the prescribing doctor immediately for further information** – they may need to modify the next infusion of Columvi (glofitamab).