Reporting of side effects

▼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. If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this document. You can also report side effects directly (see details below).

Please report side effects to:
The Drug Surveillance Centre,
Roche Products (Ireland) Limited,
3004 Lake Drive, Citywest,
Naas Road, Dublin 24
Tel: (01) 4690700
Email: ireland.drug_surveillance_centre@roche.com

Or report to:
HPRA Pharmacovigilance
Website: www.hpra.ie

Further Information

Talk to your doctor, nurse or pharmacist if you have any questions or concerns.

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FOR USE IN IRELAND

Important Safety Information for Patients receiving Columvi▼ (glofitamab) Patient Card

- Please carry this card with you at all times while you are receiving *Columvi (glofitamab)*.
- Show this card to any healthcare professional involved in your care.
- Please read this material along with the Package Leaflet supplied with this medicine and also available on www.medicines.ie before taking this medicine.

Information for the Patient

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

- Fever (100.4°F/38°C or higher)
- Fast heartbeat
- Chills
- Shortness of breath
- Feeling dizzy or lightheaded

Experiencing any of these symptoms could be due to **Cytokine Release Syndrome**, which requires immediate evaluation by a Doctor.

Cytokine Release Syndrome

- An exaggerated inflammatory condition associated with medicines that stimulate T cells, characterised by fever and impairment to multiple organs in the body.
- May be caused by receiving *Columvi (glofitamab)* and is more likely to occur during Cycle 1 after *Columvi (glofitamab)* is given.
- Close monitoring is needed. Before each infusion, you may be given medicines which help reduce possible side effects of cytokine release syndrome.

Information for the Treating Doctor

This patient has received *Columvi (glofitamab)* – **which may cause Cytokine Release Syndrome (CRS)**.

- Evaluate the patient immediately and treat symptoms.
- If CRS is suspected, please refer to section 4.2 of the SmPC of *Columvi* for comprehensive instructions on CRS management.
- **Contact the prescribing doctor** when possible – they may need to modify the next infusion of *Columvi (glofitamab)*.

Contact Information

Patient's name:

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Prescribing Doctor's name:

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Prescribing Doctor's phone number:

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Date of *Columvi (glofitamab)* initiation:

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