

## Information Card for the Patient under Treatment with

# ▼ **TECVAYLI® (teclistamab)**

You must carry this card with you at all times.

**SHOW THIS CARD** to any healthcare professional involved in your care and if you go to the hospital.

▼ This medicine is subject to additional monitoring, the notification of suspected adverse reactions associated with this medication is a priority

**Information on risk prevention agreed with the Spanish Agency of Medicines and Medical Devices (AEMPS) - January 2024**

Available on the AEMPS website [www.aemps.gob.es](http://www.aemps.gob.es)

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**Tecvayli® can cause adverse effects such as Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).**

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### **IMPORTANT SAFETY INFORMATION FOR PATIENTS**

Get medical help right away if you experience any of the following, as these are typical symptoms of the above adverse effects:

#### Cytokine Release Syndrome (CRS)

- Fever (38°C or higher)
- Chills
- Fast heartbeat
- Difficulty breathing
- Nausea
- Headache
- Feeling dizzy

#### Neurologic toxicity, including ICANS

- Feeling confused
- Feeling less alert
- Having difficulty writing
- Having difficulty speaking
- Sleepiness
- Loss of ability to carry out skilled movements and gestures (despite having the physical ability and desire to perform them)

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### **INFORMATION FOR PATIENTS IMPORTANT TO REMEMBER**

**Stay close to the location where you received your Tecvayli® therapy for at least 2 days for daily monitoring after administration of your first three doses (usually two step-up doses and the first maintenance dose).** These are not all the possible side effects of Tecvayli®. **Tell your doctor if you have any side effect that bothers you or does not go away.**

If you experience any type of adverse event, contact your doctor or pharmacist, even if you are dealing with possible adverse events that do not appear in the package leaflet. You can also report them directly through the Spanish Pharmacovigilance System for Medicinal Products for human use: <https://www.notificaRAM.es>

# Contact details of the healthcare professional

Physician's name

Hospital Name & Address

Phone number

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## Information for Healthcare Team to Fill In

Please give this card to your healthcare team to fill in the information and return it to you.

Dates of Tecvayli® (injections (step-up dosing schedule):

STEP-UP DOSE 1

STEP-UP DOSE 2

FIRST MAINTENANCE DOSE\*

\*This is the first full treatment dose (1.5 mg/kg)

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## IMPORTANT SAFETY INFORMATION FOR HEALTHCARE PROFESSIONALS

Cytokine release syndrome (CRS) and neurologic toxicity, including ICANS, may occur in patients receiving Tecvayli®, can be fatal or life-threatening, and may affect various organs or systems. The majority of these events observed following Tecvayli® administration were Grade 1 and 2.

Assess the patient for signs and symptoms of CRS and ICANS. If your patient reports any signs or symptoms as referenced on this card, please contact the patient's treating physician immediately for further information.

See Tecvayli®'s Summary of Product Characteristics for further details.

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