

Patient Card

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.

Information on risk prevention agreed with the Spanish Agency for Medicines and Health Products (AEMPS) - November 2024

Available on the AEMPS we site www.aemps.gob.es

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

Patient's name:

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Important Safety Information for Patients

Get medical help straight away if you experience any of the following (and others that are not included):

Cytokine Release Syndrome (CRS)

- Fever
- · Low blood pressure
- Chills
- · Difficulty breathing
- Fatique
- Headache
- Fast heartbeat
- Increased level of liver enzymes in the blood

Neurologic toxicity, including ICANS

- · Feeling confused
- · Feeling less alert
- · Feeling disorientated
- · Feeling sleepy
- · Slow or difficulty thinking
- Altered thinking or decreased consciousness
- Confusion
- Difficulty speaking and understanding speech

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IMPORTANT TO REMEMBER: Stay close to the location where you received your TALVEY therapy for at least 2 days for daily monitoring after administration of all doses of the step-up dosing schedule.

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 notify them directly through the Spanish Pharmacovigilance System of medicines for human use: https://www.notificaRAM.es

Treating Physician

Treating physician's name:
Treating physician's phone number(s):
Hospital name and address:

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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 to you.

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

DOSIS DE ESCALADO 1

STEP-UP DOSE 2

STEP-UP DOSE 3

STEP-UP DOSE 4*

TREATMENT PHASE[‡]

*For the biweekly dosing only. ‡ For the weekly dosing this is: 0.4 mg/kg once every week thereafter. For the biweekly dosing this is: 0.8 mg/kg once every two weeks thereafter.

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Important Safety Information for Healthcare Professionals

CRS and neurologic toxicity, including ICANS, may occur in patients receiving TALVEY, and can be fatal or life-threatening. The majority of these events observed following TALVEY 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 Summary of Product Characteristics for full details.

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▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.