TALVEY™ (talquetamab) ▼ 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

TALVEY can cause side effects such as Cytokine Release Syndrome (CRS) and neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).[1]

PATIENT'S NAME:

_____

Important Safety Information for Patients

Get medical help straight away if you experience any of the following:

Cytokine Release Syndrome (CRS)

- Fever
- Low blood pressure
- Chills
- Difficulty breathing
- Fatigue
- 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

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 have **any** of the symptoms listed on this card, call your doctor, or seek emergency medical attention right away! These are not all the possible side effects of TALVEY. Tell your doctor if you have any side effect that bothers you or does not go away.

Treating Physician

TREATING PHYSICIAN'S NAME:

_____

TREATING PHYSICIAN'S PHONE NUMBER:

_____

HOSPITAL NAME AND ADDRESS:

_____

PHONE NUMBER:

_____

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):

STEP-UP DOSE 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.

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.[1]

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.

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

Reporting of side effects

TALVEY is a new medicine and its safety is being closely monitored. Contact your doctor, pharmacist or nurse if you experience side effects with any medication you are taking. This includes any side effects that are not listed on the information leaflet that comes with this medication.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to:

- P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta
- E: postlicensing.medicinesauthority@gov.mt

Alternatively, to report Suspected Adverse Drug Reactions, contact Janssen's Local Representative, AM Mangion, on the following:

- Phone (24/7): 00356 2397 6333
- Email: pv@ammangion.com

1. TALVEY EU Summary of Product Characteristics.

EM-137750/TAL/0823/007

Date of HA approval: October 2023

The additional Risk Minimization Materials are a condition of the Marketing Authorisation.