My name: _____

My contact number: _____

Emergency contact: _____

Emergency contact number: _____

Name of Haematologist/Oncologist/ Oncology Nurse: _____

Contact number: _____

Name of my Hospital: _____

My Hospital contact number: _____

PADCEV start date: _____

# PADCEV®

(enfortumab vedotin)

## PATIENT CARD

astellas

v.01: This Patient Card format and content have been updated and approved by the Ministry of Health on 12.2022

VV-PVG-007366

- Carry this card with you **at all times**, especially when you travel or when you see another doctor.
- Please ensure you show this card to any doctor, pharmacist or nurse for any medical treatment or at any visits to the hospital or clinic.
- Please contact your doctor **immediately**, if you develop any side effects, in particular those listed on this card.

## IMPORTANT SAFETY INFORMATION FOR PATIENTS

**Padcev may cause serious side effects, including severe skin reactions (Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN) and other severe rashes such as symmetrical drug related intertriginous and flexural exanthaema).**

Talk to your doctor, pharmacist or nurseTalk to your doctor, pharmacist or nurse immediately if you have any of the following symptoms:

- rash or itching that continues to get worse or comes back after treatment,
- skin blistering or peeling,
- painful sores or ulcers in mouth or nose, throat, or genital area,
- fever or flu like symptoms,
- or swollen lymph nodes.

These may be signs of a severe skin reaction that can happen while receiving this medicine, particularly during the first few

weeks of treatment. If it occurs, your doctor will monitor you and may give you medicine to treat your skin condition. She or he may pause or stop treatment if your skin reaction worsens. If you have any further questions about your treatment, please contact your doctor.

## IMPORTANT INFORMATION FOR HEALTHCARE PROVIDERS

- This patient is being treated with Padcev (enfortumab vedotin), which can cause severe skin reactions, including SJS and TEN (predominantly during the first cycle of treatment).
- Symptoms include rash or itching that continues to get worse or comes back after treatment, skin blistering or peeling, painful sores or ulcers in mouth or nose, throat, or genital area, fever or flu-like symptoms or swollen lymph nodes.
- Fever or flu-like symptoms may be the first sign of a skin reaction. Patients should be monitored starting with the first cycle and throughout treatment for skin reactions. Topical corticosteroids/antihistamines can be considered for mild to moderate skin reactions.
- If SJS or TEN is suspectedor if bullous lesions occur, **immediately** withhold treatment and refer for specialised care; histologic confirmation is critical to early recognition, as diagnosis and intervention can improve prognosis.
- If SJS or TEN, Grade 4 or recurrent Grade 3 skin reactions occur, permanently discontinue treatment.
- Withhold treatment for Grade 2 with fever, worsening Grade 2 or Grade 3 skin reactions until Grade ≤1 and resume at the same dose level or consider dose reduction by one dose level; consider referral to specialised care.

**Please contact the patient's Oncologist for more information and consultion.**

Additional information for the patient is also available in the PADCEV Patient Booklet that should be shared with you via your doctor and also available at: https://israeldrugs.health.gov.il/#!/medDetails/16737%2036604%2000

Adverse events reporting: Adverse events can be reported directly to the Ministry of Health using the adverse events digital form which available on the home page of the Ministry of Health website: www.health.gov.il or by this link: https://sideeffects.health.gov.il/

Adverse events can also be reported to Astellas Pharma International B.V using the following email: Pharmacovigilance.IL@astellas.com