PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Astellas

December 2023

Subject:	**Patient Information Pack for Risk of Skin Reactions including Severe Cutaneous Adverse Reactions (SCAR) in patients treated with PADCEV™ (enfortumab vedotin)**

Dear Healthcare Professional,

This letter is to inform you about the **Patient Information Pack** that includes important safety information for patients about the risk of skin reactions including SCAR with PADCEV™, a Nectin-4-directed antibody drug conjugate indicated as monotherapy for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and a programmed death receptor-1 or programmed death-ligand 1 inhibitor. This letter also provides information about the PADCEV™ **Patient Information Pack** and the steps to take to provide it to patients prior to initiating treatment with PADCEV™.

The information included in the **Patient Information Pack** is considered necessary to minimize the risk of skin reactions in patients treated with PADCEV™ as SCAR is a potentially fatal complication that can progress rapidly if treatment is delayed and early intervention is essential for protection of a patient's health.

Summary

- PADCEV™ can cause severe and fatal cutaneous adverse reactions including Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN), which occurs predominantly during the first cycle of treatment, but may occur later.
- A **Patient Information Pack** has been included in each pack of the medicinal product to provide patients with important safety information about the risk of SCAR with PADCEV™ and to inform them that they should immediately seek medical care when they experience signs or symptoms of a severe skin reaction.
- The **Patient Information Pack** that is included with each PADCEV™ product pack includes:
    1. Patient Information Leaflet
    2. Patient Card – see also a copy attached to this letter.

Recommendations to Healthcare Professional

- Provide and review the **Patient Information Pack** with your patients before starting PADCEV™.
- Add contact details of the treating physician who has prescribed PADCEV™ to the Patient Card.

Version 2.0 approved 28-Nov-2023

- Please instruct your patients to carry the Patient Card with them at all times and show it to any healthcare professional they might interact with for any medical treatment (including pharmacy), or at any visits to the hospital or clinic.
- Tell your patients to talk to you immediately or go to the nearest hospital emergency room if they develop 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.

For prescribing information including a complete description of the benefits and risks related to the use of PADCEV™, please refer to the PADCEV™ Summary of Product Characteristics available on the HPRA website, www.hpra.ie and on www.medicines.ie.

For digital copies of the Patient Information Pack: please visit the HPRA website www.hpra.ie or www.medicines.ie.

For requesting additional printed copies of the Patient Information Pack: irishdrugsafety@astellas.com.

Reporting of suspected adverse reactions

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Website: www.hpra.ie.

Astellas is committed to ensuring the safe use of PADCEV™ and to collecting and reporting suspected adverse reactions during the use of PADCEV™.

Please report any suspected adverse reactions to:

Astellas Drug Safety
Tel: +353 1 467 1555
Email: irishdrugsafety@astellas.com

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Should you have any questions regarding the contents of this letter or the use of PADCEV™, please contact: medinfo.est-m@astellas.com.

Sincerely,

Olga Wedemeier
Head of Medical Affairs
Senior Medical Director BeNeLux and Ireland
Astellas Pharma Europe

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Version 2.0 approved 28-Nov-2023