17-07-2026

PADCEV™ (enfortumab vedotin) Patient Information Pack on the Risk of Skin Reactions, Including Severe Cutaneous Adverse Reactions (SCARs)

Dear Healthcare Professional,

Astellas Pharma Europe B.V., in agreement with the Malta Medicines Authority, would like to inform you of the following:

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 severe cutaneous adverse reactions 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**

Background on safety concerns

PADCEV™, is 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.

Recommendations to Healthcare Provider

- 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.
- 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 provided with this letter.

For digital copies of the Patient Information Pack:
drugsafety@novagem.com.cy

For requesting additional printed copies of the Patient Information Pack:
drugsafety@novagem.com.cy, Call center: (+357) 22483858, (09.00 - 17.00, GMT+2)

Call for reporting

▼ 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.

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

Healthcare professionals and patients are encouraged to report any suspected adverse reactions. Please report adverse events in accordance with your national spontaneous reporting system:

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form available online at http://www.medicinesauthority.gov.mt/adrportal and sent to Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN or sent by email to: postlicensing.medicinesauthority@gov.mt.

Company contact point

Alternatively, suspected adverse reactions should be reported to Novagem Ltd at the email drugsafety@novagem.com.cy, Call center: (+357) 22483858, (09.00 - 17.00, GMT+2)

Should you have any questions regarding the contents of this letter or the use of PADCEV™, please contact Novagem Ltd at the Call center: (+357) 22483858, (09.00 - 17.00, GMT+2).

Sincerely,

Georgia Antoniou
Local RPPV
Novagem Ltd

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