CONTENT OF PATIENT CARD

PATIENT CARD

PADCEV
(enfortumab vedotin)

- 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 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 suspected or 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 Haematologist/Oncologist for more information and consult the Product Information for enfortumab vedotin available at https://www.ema.europa.eu/.

My name: _____
My contact number: _____
Emergency contact: _____
Emergency contact number: _____
Name of Haematologist/Oncologist/Oncology Nurse: _____
Contact number: _____
After-hours contact number: _____
Name of my Hospital: _____
My Hospital contact number: _____
PADCEV start date:_____

PACKAGE LEAFLET

Package leaflet: Information for the patient

Padcev 20 mg powder for concentrate for solution for infusion
Padcev 30 mg powder for concentrate for solution for infusion
enfortumab vedotin

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Padcev is and what it is used for
2. What you need to know before you are given Padcev
3. How to use Padcev
4. Possible side effects
5. How to store Padcev
6. Contents of the pack and other information

1. What Padcev is and what it is used for

Padcev contains the active substance enfortumab vedotin which is made up of a monoclonal antibody linked to a substance intended to kill cancer cells. The monoclonal antibody recognises certain cancer cells and delivers the substance to the cancer cells.

This medicine is used in adults to treat a kind of cancer called bladder cancer (urothelial carcinoma). People get Padcev when their cancer has spread or cannot be taken out by surgery.

Padcev is given to people that have received an immunotherapy medicine and also received a chemotherapy-containing platinum medicine.

2. What you need to know before you are given Padcev

You must not be given Padcev

- if you are allergic to enfortumab vedotin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor immediately if you:

- have any of the following skin reaction 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 your treatment. If it occurs, your doctor will monitor you and may give you a medicine to treat your skin condition. She or he may pause treatment until symptoms are reduced. If your skin reaction worsens, your doctor may stop your treatment. You will also find this information in the Patient Card that is included in the packaging. It is important that you keep this Patient Card with you and show it to any healthcare professional you see.

– have any symptoms of high blood sugar, including frequent urination, increased thirst, blurred vision, confusion, drowsiness, loss of appetite, fruity smell on your breath, nausea, vomiting, or stomach pain. You can develop high blood sugar during treatment.

– have any symptoms of nerve problems (neuropathy) such as numbness, tingling or a tingling sensation in your hands or feet or muscle weakness. If it occurs, your doctor may pause treatment until symptoms are improved or reduce your dose. If your symptoms worsen, your doctor may stop your treatment.

– have eye problems such as dry eyes during your treatment. You can develop dry eye problems while receiving Padcev.

Children and adolescents

This medicine should not be used in children and adolescents below 18 years of age.

Other medicines and Padcev

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you take medicines for fungal infections (e.g., ketoconazole) as they can increase the amount of Padcev in your blood. If you normally take these medicines, your doctor might change it and prescribe a different medicine for you during your treatment.

Pregnancy and breast-feeding and fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before starting this medicine.

You should not use this medicine if you are pregnant. Padcev may harm your unborn baby.

If you are a woman starting this medicine who is able to become pregnant, you should use effective contraception during treatment and for at least 12 months after stopping Padcev.

It is not known if this medicine passes into your breast milk and could harm your baby. Do not breast-feed during treatment and for at least 6 months after stopping Padcev.

Men being treated with this medicine are advised to have sperm samples frozen and stored before treatment. Men are advised not to father a child during treatment with this medicine and for up to 9 months following the last dose of this medicine.

Driving and using machines

Do not drive or operate machines if you feel unwell during treatment.

3. How to use Padcev

You will receive Padcev in a hospital or clinic, under the supervision of a doctor experienced in giving such treatments.

How much Padcev you will receive

The recommended dose of this medicine is 1.25 mg/kg on days 1, 8 and 15 every 28 days. Your doctor will decide how many treatments you need.

How you will receive Padcev

You will receive Padcev by intravenous infusion into your vein over 30 minutes. Padcev will be added to an infusion bag containing either glucose, sodium chloride or Lactated Ringer's solution before use.

If you miss a dose of Padcev

It is very important for you to keep all of your appointments to receive Padcev. If you miss an appointment, ask your doctor when to schedule your next dose.

If you stop receiving Padcev

Do not stop treatment with Padcev unless you have discussed this with your doctor. Stopping your treatment may stop the effect of the medicine.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some possible side effects may be serious:

- **Skin reactions (Stevens-Johnson syndrome, toxic epidermal necrosis and other severe rashes such as symmetrical drug related intertriginous and flexural exanthaema).** Tell your doctor right away if you have any of these signs of a severe skin reaction: 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 (frequency not known).

- **High blood sugar (hyperglycaemia).** Tell your doctor right away if you have any symptoms of high blood sugar, including: frequent urination, increased thirst, blurred vision, confusion, drowsiness, loss of appetite, fruity smell on your breath, nausea, vomiting or stomach pain (may affect up to 1 in 10 people).

- **Nerve problems (peripheral neuropathy such as motor neuropathy, sensimotor neuropathy, paraesthesia, hypoaesthesia and muscular weakness).** Tell your doctor right away if you get numbness, tingling or a tingling sensation in your hands or feet or muscle weakness (may affect up to 1 in 100 people).

- **Leakage of Padcev out of your vein into the tissues around your infusion site (extravasation)**. Tell your doctor or get medical help right away if you notice any redness, swelling, itching, or discomfort at the infusion site. If Padcev leaks from the injection site or the vein into the nearby skin and tissues, it could cause an infusion site reaction. These reactions can happen right after you receive an infusion, but sometimes may happen days after your infusion (may affect up to 1 in 100 people).

Other possible side effects

Very common (may affect more than 1 in 10 people):

- low red blood cells (anaemia)
- nausea, diarrhoea and vomiting
- tiredness
- decreased appetite
- change in sense of taste
- dry eye
- hair loss
- weight loss
- dry or itchy skin
- rash
- flat or red raised bumps on the skin
- increased liver enzymes (aspartate aminotransferase [AST] or alanine aminotransferase [ALT])

Common (may affect more than 1 in 100 people):

- abnormal walking (gait disturbance)
- eye redness
- hives on the skin
- redness in the skin
- inflamed, itchy, cracked and rough patches of skin
- redness and tingling on the palms or soles of feet
- skin peeling
- mouth ulcer
- rash with accompanying symptoms: itchiness, redness, red bumps or red patches on the skin, fluid-filled blisters, large blisters, skin lesions

Uncommon (may affect more than 1 in 1000 people):

- skin irritation
- skin burning sensation
- problems affecting nerve function causing odd sensation or problems with movement
- muscle decreasing in size
- blood blister
- allergic reaction to skin
- rash with accompanying symptoms: spots that look like bullseyes, skin peeling, flat fluid-filled blister
- skin peeling all over the body
- inflammation in skin folds including the groin
- blister or blister-like lesions on the skin
- inflammation or itchiness appearing on the legs and feet only

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

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National Agency for Medicines
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GR-15562 Cholargos, Athens

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Fax: +30 21 06549585
Website: http://www.eof.gr

Cyprus
Pharmaceutical Services
Ministry of Health
CY-1475 Nicosia
Tel: +357 22608607
Fax: + 357 22608669
Website: www.moh.gov.cy/phs

5. How to store Padcev

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2ºC to 8ºC). Do not freeze.

Do not store any unused portion of the infusion solution for reuse. Any unused medicine or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Padcev contains

- The active substance is enfortumab vedotin.
- One vial of 20 mg powder for concentrate for solution for infusion contains 20 mg of enfortumab vedotin
- One vial of 30 mg powder for concentrate for solution for infusion contains 30 mg of enfortumab vedotin
- After reconstitution, each mL of solution contains 10 mg of enfortumab vedotin

The other ingredients are histidine, histidine hydrochloride monohydrate, trehalose dihydrate and polysorbate 20.

What Padcev looks like and contents of the pack

Padcev powder for concentrate for solution for infusion is a white to off-white lyophilized powder. Padcev is supplied in a box containing 1 glass vial.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Astellas Pharma Europe B.V.
Sylviusweg 62
2333 BE Leiden
The Netherlands

Manufacturer:
Astellas Ireland Co. Ltd
Killorglin
Co Kerry
V93 FC86

Ireland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
Astellas Pharma B.V. Branch
Tél/Tel: +32 (0) 2 5580710

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Free call from Northern Ireland: 0800783 5018

This leaflet was last revised in 04/2022.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

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The following information is intended for healthcare professionals only:

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Instructions for preparation and administration

Reconstitution in single-dose vial

1. Follow procedures for proper handling and disposal of anticancer medicinal products.
2. Use appropriate aseptic technique for reconstitution and preparation of dosing solutions.
3. Calculate the recommended dose based on the patient's weight to determine the number and strength (20 mg or 30 mg) of vials needed.
4. Reconstitute each vial as follows and, if possible, direct the stream of sterile water for injection along the walls of the vial and not directly onto the lyophilized powder:
   a. 20 mg vial: Add 2.3 mL of sterile water for injection, resulting in 10 mg/mL enfortumab vedotin.
   b. 30 mg vial: Add 3.3 mL of sterile water for injection, resulting in 10 mg/mL enfortumab vedotin.
5. Slowly swirl each vial until the contents are completely dissolved. Allow the reconstituted vial(s) to settle for at least 1 minute until the bubbles are gone. Do not shake the vial.
6. Visually inspect the solution for particulate matter and discolouration. The reconstituted solution should be clear to slightly opalescent, colourless to light yellow and free of visible particles. Discard any vial with visible particles or discolouration.

Dilution in infusion bag

7. Withdraw the calculated dose amount of reconstituted solution from the vial(s) and transfer into an infusion bag.
8. Dilute enfortumab vedotin with dextrose 50 mg/mL (5%), sodium chloride 9 mg/mL (0.9%) or Lactated Ringer's solution for injection. The infusion bag size should allow enough solvent to achieve a final concentration of 0.3 mg/mL to 4 mg/mL enfortumab vedotin.

Diluted dosing solution of enfortumab vedotin is compatible with intravenous infusion bags composed of polyvinyl chloride (PVC), ethylvinyl acetate, polyolefin such as polypropylene (PP), or IV bottles comprised of polyethylene (PE), polyethylene terephthalate glycol-modified, and infusion sets composed of PVC with either plasticizer (bis(2-ethylhexyl) phthalate (DEHP) or tris(2-ethylhexyl) trimellitate (TOTM)), PE and with filter membranes (pore size : 0.2-1.2 μm) composed of polyethersulfone, polyvinylidene difluoride, or mixed cellulose esters.

9. Mix diluted solution by gentle inversion. Do not shake the bag.
10. Visually inspect the infusion bag for any particulate matter or discolouration prior to use. The reconstituted solution should be clear to slightly opalescent, colourless to light yellow and free of visible particles. Do not use the infusion bag if particulate matter or discolouration is observed.
11. Discard any unused portion left in the single-dose vials.

Administration

12. Administer the infusion over 30 minutes through an intravenous line. Do not administer as an intravenous push or bolus.

No incompatibilities have been observed with closed system transfer device composed of acrylonitrile butadiene styrene(ABS), acrylic, activated charcoal, ethylene propylene diene monomer, methacrylate ABS, polycarbonate, polyisoprene, polyoxymethylene, PP, silicone, stainless steel, thermoplastic elastomer for reconstituted solution.

13. Do not co-administer other medicinal products through the same infusion line.
14. In-line filters or syringe filters (the pore size: 0.2-1.2 μm, recommended materials: polyethersulfone, polyvinylidene difluoride, mixed cellulose esters) are recommended to be used during administration.

Disposal

Padcev is for single use only.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.