PADCEV™

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about being given this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the full CMI for further details.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I being given PADCEV?

PADCEV contains the active ingredient enfortumab vedotin. PADCEV is used alone or in combination with pembrolizumab in adults to treat a kind of cancer called urothelial cancer (urothelial carcinoma). People get PADCEV when their cancer has spread or cannot be taken out by surgery.
For more information, see Section 1. Why am I being given PADCEV? in the full CMI.

2. What should I know before I am given PADCEV?

PADCEV should not be given if you have ever had an allergic reaction to enfortumab vedotin or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. PADCEV should not be given to children and adolescents below 18 years of age.
For more information, see Section 2. What should I know before I am given PADCEV? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with PADCEV and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How am I given PADCEV?

- Your doctor will give you PADCEV through an infusion (a drip) into a vein (intravenously) over 30 minutes.
- If you get PADCEV alone, you will get PADCEV once a week for 3 weeks in each 28 day period of treatment.
- If you get PADCEV with pembrolizumab, you will get PADCEV once a week for 2 weeks in each 21 day period of treatment.
- Your doctor will decide how many treatments you need.

More instructions can be found in Section 4. How am I given PADCEV? in the full CMI.

5. What should I know while being given PADCEV?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are being given PADCEV. • Tell your doctor if you have any symptoms of skin reactions, high blood sugar or diabetes, lung problems, nerve damage, or eye problems. • Tell your doctor if you are taking any other medicines including but not limited to treatment for fungal infections (e.g., Ketoconazole). Additional medicines are listed in Section 3. What if I am taking other medicines? in the full CMI.
Things you should not do	• It is very important that you do not miss a dose of this medicine (call your doctor if you cannot make it to your appointment to receive your next dose).
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how PADCEV affects you.
Looking after your medicine	• You will not be asked to store PADCEV. It will usually be stored in the pharmacy or on the ward. Any unused portion of the solution will be disposed of by your doctor.

For more information, see Section 5. What should I know while being given PADCEV? in the full CMI.

6. Are there any side effects?

Some possible side effects may be serious, and can include skin reactions, high blood sugar levels, lung problems, nerve damage and eye problems.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING:

SERIOUS SKIN REACTIONS

Tell your doctor right away if you have 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.

PADCEV™

Active ingredient(s): *enfortumab vedotin*

Consumer Medicine Information (CMI)

This leaflet provides important information about using PADCEV. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PADCEV.**

Where to find information in this leaflet:

1. Why am I being given PADCEV?
2. What should I know before I am given PADCEV?
3. What if I am taking other medicines?
4. How am I given PADCEV?
5. What should I know while being given PADCEV?
6. Are there any side effects?
7. Product details

1. Why am I being given PADCEV?

PADCEV contains the active ingredient enfortumab vedotin.

PADCEV is used in adults to treat urothelial carcinoma.

- PADCEV may be given with pembrolizumab.
- PADCEV may be given alone to people that have received an immunotherapy medicine and also received a platinum-containing chemotherapy medicine.

People get PADCEV when their cancer has spread or cannot be taken out by surgery.

2. What should I know before I am given PADCEV?

Warnings

Do not use PADCEV if:

- you are allergic to enfortumab vedotin, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can be given this medicine.

Check with your doctor if you:

- have high blood sugar or diabetes.
- are currently experiencing numbness or tingling in your hands or feet.
- take any other medicines including but not limited to treatment 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 with PADCEV.

During treatment, you may be at risk of developing certain side effects. These side effects can sometimes become life-threatening and can lead to death. These side effects may happen anytime during treatment or even after your treatment has ended. You may experience more than one side effect at the same time.

- It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

PADCEV may harm your unborn baby and should not be used during pregnancy.

If you are a woman starting PADCEV who is able to become pregnant, you should use effective contraception during treatment with PADCEV and for at least 7 months after stopping PADCEV.

If you are a man taking PADCEV whose partner is able to become pregnant, you should use effective contraception during treatment with PADCEV and for at least 6 months after stopping PADCEV.

It is not known if PADCEV passes into your breast milk and could harm your baby. You should not breastfeed during treatment with PADCEV and for at least 6 months after stopping PADCEV.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Medicines that may interfere with the effect of PADCEV include but are not limited to medicines for treating:

- bacterial infections (e.g., clarithromycin)
- depression (e.g., nefazodone)
- fungal infections (e.g., ketoconazole, voriconazole, posaconazole, itraconazole)
- hepatitis C (e.g., boceprevir, telaprevir)
- infections with the human immunodeficiency virus (HIV) (e.g., cobicistat, indinavir, nelfinavir, ritonavir, saquinavir)
- epilepsy (e.g., carbamazepine, phenobarbital, phenytoin)
- depression (e.g., escitalopram, fluoxetine, sertraline or the herbal medicine St. John's wort (also known as *Hypericum perforatum*))
- tuberculosis (e.g., rifampicin).

Do not take PADCEV with:

- the supplement goldenseal (*Hydrastis canadensis*).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PADCEV.

4. How am I given PADCEV?

How much to take

- PADCEV will be given to you by intravenous (IV) infusion into your vein over 30 minutes.
- Your doctor will decide how much to use.

When to take PADCEV

- You will receive your PADCEV over periods of time called cycles.
- If you receive PADCEV alone, each cycle is 28 days and you will receive PADCEV on days 1, 8 and 15 of every cycle.
- If you receive PADCEV with pembrolizumab, each cycle is 21 days and you will receive PADCEV on days 1 and 8 of every cycle.
- Your doctor will decide how many treatment cycles you need.

If you forget to receive PADCEV

If you miss a dose, call your doctor right away to reschedule your appointment. It is very important that you do not miss a dose of this medicine.

If you are given too much PADCEV

As PADCEV is given to you under the supervision of your doctor, it is unlikely that you will be given too much. However, if you experience any side effects after being given PADCEV, tell your doctor immediately.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while being given PADCEV?

Things you should do

Call your doctor straight away 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 PADCEV, particularly during the first few weeks of your treatment. The skin problems may occur in more patients when PADCEV is given with pembrolizumab than when PADCEV is used alone. If it occurs, your doctor will monitor you and may give you a medicine to treat your condition. She or he may pause PADCEV treatment until symptoms are reduced. If your skin reaction worsens, your doctor may stop your PADCEV treatment.
- 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 with PADCEV.
- have any symptoms of lung problems, including cough, shortness of breath or chest pain. The lung problems including severe events may occur in more patients when PADCEV is given with pembrolizumab than when PADCEV is used alone. 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 any symptoms of nerve damage (neuropathy) such as numbness, tingling or a tingling sensation in your hands or feet or muscle weakness, burning, stabbing or shooting pain. 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 PADCEV treatment.
- have eye problems such as dry eyes during your treatment. You can develop certain eye problems while receiving PADCEV.

Remind any doctor, dentist or pharmacist you visit that you are being given PADCEV.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how PADCEV affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

You will not be asked to store PADCEV. It will usually be stored in the fridge (at 2°C to 8°C) at the pharmacy or on the ward. Unused portion of the infusion solution will not be stored for reuse.

Getting rid of any unwanted medicine

Any unused medicine or waste material will be disposed of by your doctor in accordance with local requirements.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Bleeding related: • low red blood cells (anaemia) • decreased white blood cell count **Stomach related:** • nausea, diarrhoea and vomiting **General:** • tiredness • abnormal walking (gait disturbance) • weight loss **Eating related:** • decreased appetite • change in sense of taste **Eye related:** • dry eye **Skin related:** • hair loss • change in skin tone or abnormal darkening of the skin (skin hyperpigmentation, skin discoloration, pigmentation disorder) **Liver related:** • increased liver enzymes (aspartate aminotransferase [AST] or alanine aminotransferase [ALT]) (these are blood tests) **Endocrine related:** • underactive thyroid (hypothyroidism) This may happen when PADCEV is given in combination with pembrolizumab	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Skin reactions: • **Stevens-Johnson syndrome** • **toxic epidermal necrolysis** • **other severe rashes** 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 • 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 • stomach pain (may affect more than 1 in 10 people). **Respiratory symptoms and lung problems (lung inflammation):** • cough • shortness of breath • chest pain	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
(may affect up to 1 in 10 people). **Nerve damage (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 • muscle weakness • burning, stabbing or shooting pain (may affect more than 1 in 10 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 10 people).	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What PADCEV contains

Active ingredient **(main ingredient)**	enfortumab vedotin
Other ingredients **(inactive ingredients)**	histidine, histidine hydrochloride monohydrate, trehalose dihydrate, and polysorbate 20

Do not take this medicine if you are allergic to any of these ingredients.

What PADCEV looks like

PADCEV 20 mg is a white to off-white powder for injection in a vial. (Aust R 355870).

PADCEV 30 mg is a white to off-white powder for injection in a vial. (Aust R 367410).

Who distributes PADCEV

Astellas Pharma Australia Pty Ltd

Suite 2.01, 2 Banfield Road

Macquarie Park NSW 2113

Tel: 1800 751 755 (Medical Information)

Email: aaumedinfo@astellas.com (Medical Information)

Website: www.astellas.com/au

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