

What is in this leaflet

1. What PADCEV is used for
2. How PADCEV works
3. Before you use PADCEV
4. How to use PADCEV
5. While you are using it
6. Side effects
7. Storage and Disposal of PADCEV
8. Product Description

1. What PADCEV is used for

PADCEV contains the active substance enfortumab vedotin.

This medicine is used alone or in combination with pembrolizumab 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 when used alone is given to people that have received an immunotherapy medicine and also received a chemotherapy containing platinum medicine.

This medicine may be given in combination with pembrolizumab. It is important that you also read the package leaflet for this other medicine. If you have any questions, ask your doctor.

2. How PADCEV works

Enfortumab vedotin is made up of a monoclonal antibody linked to a substance intended to kill cancer cells. The monoclonal antibody recognizes certain cancer cells and delivers the substance to the cancer cells.

3. Before you use PADCEV

When you must not use it

If you are allergic to enfortumab vedotin or any of the other ingredients of this medicine (listed in section 8).

Pregnancy, 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. This medicine 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 6 months after stopping PADCEV.

If you are a man taking this medicine whose partner is able to become pregnant, you should use effective contraception during treatment and for at least 4 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.

Children and adolescents

The safety and efficacy of this medicine in children and adolescents have not been established.

Before you start using it

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. Skin reactions may occur in more patients when this medicine is given with pembrolizumab. 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.

- 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. You can develop high blood sugar during treatment.
- If you have lung problems (pneumonitis/interstitial lung disease) or if you get new or worsening symptoms, including trouble breathing, shortness of breath, or cough. These lung problems may occur more often when this medicine is given with pembrolizumab. 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.
- If you have, or think you have, an infection. Some infections may be serious and can be life-threatening.
- If you 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.
- If you have eye problems such as dry eyes during your treatment. You can develop dry eye problems while receiving PADCEV.

Taking other medicines

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.

4. How to use PADCEV

How much to use

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.

When to use it

When used alone, the recommended dose of this medicine is 1.25 mg/kg on days 1, 8 and 15 every 28 days. When used with pembrolizumab, the recommended dose of this medicine is 1.25 mg/kg on days 1 and 8 every 21 days. Your doctor will decide how many treatments you need.

How long to use it

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

If you forget to use it

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 use too much (overdose)

In case of overdosage, patients should be closely monitored for adverse reactions, and supportive treatment should be administered as appropriate.

5. While you are using it

Things you must do

Tell all the doctors, dentists and pharmacists treating you that are taking PADCEV.

Things you must not do

Do not take any new medicines without consulting your doctor.

Things to be careful of

Driving and using machines

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

6. 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 necrolysis and other severe rashes such as symmetrical drug-related intertriginous and flexural exanthema).** 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 (hyperglycemia).** 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 more than 1 in 10 people).
- **A serious complication of diabetes with high levels of ketones in the blood that can make blood more acidic (diabetic ketoacidosis)** (frequency not known).
- **Lung problems (pneumonitis/interstitial lung disease).** Tell your doctor right away if you get new or worsening symptoms, including trouble breathing, shortness of breath, or cough (may affect up to 1 in 10 people).
- **Nerve problems (peripheral neuropathy such as motor neuropathy, sensorimotor neuropathy, paresthesia,**
- hypoesthesia 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 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).
- **Serious infection (sepsis) when bacteria and their toxins circulate in the blood leading to organ damage** (may affect up to 1 in 10 people).
- **Infusion related reaction**
Medicines of this type (monoclonal antibodies) can cause infusion related reactions such as:
 - low blood pressure
 - tongue swelling
 - difficulty breathing (dyspnoea)
 - fever
 - chills
 - reddening of the skin (flushing)
 - itching
 - rash
 - being sick (vomiting)
 - feeling generally unwell (malaise)
- In general, these types of reactions occur within minutes to several hours following completion of the infusion. However, they may develop more than several hours after completion of the infusion but this is uncommon. Infusion-related reactions may affect up to 1 in 10 people.

Other possible side effects

The following side effects have been reported with PADCEV alone:

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

- low red blood cells (anemia)
- nausea, diarrhea 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 up to 1 in 10 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 up to 1 in 100 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

Not known (frequency cannot be estimated from the available data):

- low white blood cell count with or without fever
- discoloration or abnormal darkening of the skin (skin hyperpigmentation, skin discoloration, pigmentation disorder)

The following side effects have been reported with PADCEV in combination with pembrolizumab:

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

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

Common (may affect up to 1 in 10 people):

- abnormal walking (gait disturbance)
- eye redness
- hives on the skin
- redness in the skin
- rash
- 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: spots that look like bullseyes, itchiness, redness, red bumps or red patches on the skin, fluid-filled blisters, large blisters, skin lesions
- increased lipase (a blood test done to check your pancreas)
- inflammation of the muscles (myositis)

Uncommon (may affect up to 1 in 100 people):

- skin irritation
- skin burning sensation
- problems affecting nerve function causing odd sensation or problems with movement
- allergic reaction to skin
- rash with accompanying symptoms: 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

Not known (frequency cannot be estimated from the available data):

- low white blood cell count with or without fever
- discoloration or abnormal darkening of the skin (skin hyperpigmentation, skin discoloration, pigmentation disorder)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

7. Storage and Disposal of PADCEV

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

Enfortumab vedotin (20 mg, 30 mg)

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 (2°C to 8°C). Do not freeze.

Do not store any unused portion of the infusion solution for reuse.

Disposal

Any unused medicine or waste material should be disposed of in accordance with local requirements.

8. Product Description

What it looks like

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.

Ingredients

Active ingredient

The active substance is enfortumab vedotin.

- 1 vial contains enfortumab vedotin 20 mg or 30 mg
- After reconstitution, each mL of solution contains 10 mg of enfortumab vedotin

Inactive ingredients

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

MAL number:

20mg: MAL24096024ACZ

30mg: MAL24096025ACZ

Manufacturer

Packed and released by:

Astellas Ireland Co., Limited.
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