

Consumer Medicine Information

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.

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 is given 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)