

PART III: CONSUMER INFORMATION

PrJEVTANA®
Cabazitaxel for injection

This leaflet is part III of a three-part "Product Monograph" published when JEVTANA was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about JEVTANA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

JEVTANA, in combination with prednisone or prednisolone, is used to treat patients with metastatic prostate cancer who have received prior cancer treatment with docetaxel.

What it does:

Every cell in your body contains a supporting structure (almost like a "skeleton"). If this "skeleton" is damaged, the cell can not grow or divide.

JEVTANA makes the "skeleton" in cells unnaturally stiff, so the cancer cells then can no longer grow or divide.

When it should not be used:

- if you experienced severe allergy (hypersensitivity) to:
 - JEVTANA or any of the other ingredients in the formulation or components of the container; or
 - to other medicine containing the same nonmedicinal ingredients (polysorbate 80).
- if the number of your white blood cells is too low.
- if you have a severe liver disease.
- if you have recently received or you are about to receive a live vaccine such as yellow fever vaccine.

What the medicinal ingredient is:

Cabazitaxel

What the important nonmedicinal ingredients are:

Polysorbate 80 (including citric acid) and ethanol.

What dosage forms it comes in:

JEVTANA is a concentrated solution for injection and is available in a vial. Each vial contains 60mg/1.5 ml cabazitaxel. JEVTANA is to be diluted with a diluent provided with the product.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

JEVTANA should only be administered by a qualified healthcare professional experienced in the use of anticancer treatments.

Possible serious side effects with the use of JEVTANA include:

- Serious allergic reactions
- Low white blood cell count that may result in life-threatening infection and death
- Gastrointestinal reactions (such as bleeding and perforation) that may result in death

BEFORE or WHILE you use JEVTANA talk to your doctor, nurse or pharmacist if:

- You have a fever. A fever is the earliest sign of infection which may be caused by reduced white blood cell count.
- You have any allergies. Antiallergic medicines will be given to you to reduce the risk of an allergic reaction, as JEVTANA may also cause serious allergic reactions (hypersensitivity).
- You have severe or persistent diarrhea, nausea or vomiting which may result in dehydration.
- You have liver or kidney problems.
- You have heart problem or irregular heart rate.
- You are going to have any vaccines. JEVTANA should not be used if you have recently received or you are about to receive a live vaccine (such as yellow fever vaccine), since concomitant use may result in serious life-threatening infections.

JEVTANA might be present in your semen. Use a condom every time you have sexual intercourse with a woman who is pregnant or can get pregnant while you are taking JEVTANA and for 6 months after your last dose of JEVTANA.

JEVTANA may cause fatigue or dizziness. If you experience these symptoms, do not drive or use any tools or machines.

INTERACTIONS WITH THIS MEDICATION

Please tell your doctor or your hospital pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may affect the way JEV TANA works or JEV TANA may affect how other medicines work.

These medicines include the following:

- medicines used to treat infections, such as: ketoconazole, rifampicin, clarithromycin, indinavir, nelfinavir, ritonavir, saquinavir, voriconazole
- medicines used to treat seizures, such as: carbamazepine, phenytoin, phenobarbital.

PROPER USE OF THIS MEDICATION

Usual dose:

JEV TANA will be given to you as an infusion into the vein (intravenous infusion) by a healthcare professional.

Your doctor will decide the dose that you should receive based on your height and weight.

The infusion will take about 1 hour.

During treatment with JEV TANA you will also need to take prednisone by mouth every day.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

This medicine needs to be given on a fixed schedule. If you miss an appointment, call your doctor or nurse for instructions.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, JEV TANA can cause side effects.

Very common side effects may include:

- low white blood cell count, which may cause infections and fever
- low red blood cell count (anemia), which may cause shortness of breath and fatigue
- low blood platelets that may lead to bleeding
- diarrhea, nausea, vomiting, constipation, abdominal pain
- decreased appetite
- change in the sense of taste
- blood in the urine (hematuria)
- allergic reactions
- hair loss
- tiredness
- muscle or joint pain
- back pain
- weakness
- cough

- shortness of breath
- fever

Common side effects may include:

- low blood pressure
- decreased amount of urine and swelling of the face, legs or body (kidney failure)
- headache
- dizziness
- numbness, tingling, burning or decreased sensation in the hands and feet
- muscle spasms
- dehydration
- urinary tract infection

Tell your doctor about any side effects that you might have during treatment with JEV TANA.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Common			
Fever, chills or signs of infection, like redness or swelling at the injection site, a cough that brings up mucus, or a sore throat		√	
Persistent vomiting or diarrhea; abdominal pain, abdominal tenderness, persistent constipation, dark stool or blood in stool.		√	
Kidney symptoms such as blood in the urine, urinary incontinence, decreased amount of urine, pain while urinating, swelling, especially in legs and feet, feeling confused, anxious, restless or sleepy, pain in the back just below the rib cage.		√	
Unusual bleeding or bruising, black or tarry stools, blood in the urine		√	
Extreme weakness or fatigue		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Radiation cystitis (inflammation of the bladder in patients that have received radiotherapy) with symptoms such as: persistent urge to urinate; a burning sensation or pain when urinating; passing frequent, small amounts of urine; blood in the urine (hematuria).		√	
Uncommon			
Allergic reactions such as trouble breathing, tightness in the throat, rash, hives, swelling of the lips or tongue or low blood pressure		√	
Unknown frequency			
Respiratory problems with symptoms such as: difficulty breathing, shortness of breath, cough, fatigue.			√
Vein thrombosis: blood clot formed in one or more of the veins in your body (usually in the legs or lungs), with symptoms such as: leg pain or swelling; shortness of breath, chest pain, cough; sweating, rapid or irregular heartbeat, dizziness.		√	

This is not a complete list of serious side effects. For any unexpected effects while taking JEV TANA, contact your doctor or pharmacist.

HOW TO STORE IT

The unopened vials should be stored at room temperature between 15°C to 30°C.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.sanofi.ca>, or by contacting the sponsor, sanofi-aventis Canada Inc., at: 1-800-265-7927

This leaflet was prepared by sanofi-aventis Canada Inc.

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