

# Jevtana®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using Jevtana?

Jevtana contains the active ingredient cabazitaxel. Jevtana is used to treat prostate cancer that has progressed after having had other chemotherapy. For more information, see Section [1. Why am I using Jevtana?](#) in the full CMI.

### 2. What should I know before I use Jevtana?

Do not use if you have ever had an allergic reaction to cabazitaxel or any of the ingredients listed at the end of the CMI.

Do not use if the number of your white blood cells is too low, you have a liver disease or if you have recently received or are about to receive a vaccine against yellow fever.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or if your partner is pregnant, plans to become pregnant or breastfeed.** For more information, see Section [2. What should I know before I use Jevtana?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with Jevtana 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 is Jevtana given?**

- Jevtana will be given by infusion into one of your veins (intravenous use). The infusion will last approximately 1 hour during which you will be in the hospital.
- You usually receive your infusion once every 3 weeks.

More instructions can be found in Section [4. How is Jevtana given?](#) in the full CMI.

### **5. What should I know while using Jevtana?**

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, pharmacist or nurse you visit that you are using Jevtana.</li></ul>
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	<ul style="list-style-type: none"> <li>• Use a condom during sex if your partner is or could become pregnant.</li> <li>• Call your doctor immediately if your partner becomes pregnant while you are being given this medicine</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine unless your doctor tells you to</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how Jevtana affects you.</li> <li>• If you experience symptoms such as fatigue or dizziness, do not drive or use any tools or machines until they have fully resolved.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Jevtana is stored in the pharmacy or on the ward. Do not store at home.</li> <li>•</li> </ul>

For more information, see Section [5. What should I know while using Jevtana ?](#) in the full CMI.

## 6. Are there any side effects?

Very common side effects include: feeling tired, weak or lack of energy; symptoms of anaemia like tiredness, and inability to perform daily tasks (due to a decrease in the number of red blood cells); increased bleeding (due to a decrease in the number of platelets); loss of appetite (anorexia); alteration in sense of taste; shortness of breath; cough; stomach upsets including nausea, vomiting and diarrhoea, constipation; abdominal pain; short term hair loss (in most cases normal hair growth should return after treatment has stopped); back pain; joint pain; blood in the urine.

Serious side effects include: symptoms of allergic reaction; fever; dehydration (possibly following severe or long-lasting diarrhoea, or vomiting; signs of infection such as fever, chills, sweats, feeling tired or fatigued.

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.

# Jevtana<sup>®</sup> (jev-ta-na)

**Active ingredient(s):** *cabazitaxel* (ca-ba-zi-tax-el)

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Jevtana. **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 Jevtana.**

**Where to find information in this leaflet:**

- [1. Why am I using Jevtana?](#)
- [2. What should I know before I use Jevtana?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Jevtana given?](#)
- [5. What should I know while using Jevtana?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Jevtana?

**Jevtana contains the active ingredient cabazitaxel.** It belongs to a group of medicines called 'taxanes' used to treat cancers.

**Jevtana is used to treat prostate cancer that has progressed after having had other chemotherapy.**

It works by stopping cells from growing and multiplying.

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## **2. What should I know before I use Jevtana?**

### **Warnings**

#### **Do not receive Jevtana if:**

- the number of your white blood cells is too low (neutrophil counts of 1,500 per cubic millimetre, or less - your doctor will advise you on this),
- you have a liver disease
- you have recently received or are about to receive a vaccine against yellow fever
- you are allergic to cabazitaxel, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

#### **Check with your doctor if you:**

- have any other medical conditions, especially:
  - a fever (during treatment with Jevtana, it is more likely that your white blood cell count may be

reduced). Your doctor will monitor your blood and general condition for signs of infections.

- any allergies, especially to ingredients listed at the end of this leaflet
- lung, liver or kidney problems
- any stomach problems past or present (including ulcers)
- severe or long-lasting diarrhoea, nausea or vomiting. Any of these events could cause dehydration. Your doctor may need to treat you.
- have a feeling of numbness, tingling, burning or decreased sensation in your hands or feet
- have any bleeding from the gut that may cause changes in the colour of your stool or stomach pain.
- suffer from alcoholism, liver disease or epilepsy/seizures. Jevtana contains alcohol (13% w/w ethanol, equivalent to 14 ml of beer or 6 ml of wine)
- take any medicines for any other condition, especially medicines used to prevent blood clots and oral non-steroidal anti-inflammatories (NSAIDs).
- have previously received radiation therapy. Inflammation of the bladder may also occur. Tell your doctor, nurse or pharmacist if you have burning sensation when passing urine.
- plan to have surgery.

During treatment, you may be at risk of developing certain side effects. 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

Jevtana could adversely affect your baby. Tell your doctor if your partner is pregnant or breastfeeding. Tell your doctor if your partner intends to become pregnant or breastfeed. The use of effective contraception in male patients with partners who may become pregnant is recommended during treatment and for 6 months after the final treatment is given. Jevtana might be present in your semen. Therefore, the use of a condom is always recommended during sexual intercourse.

## Adolescents and children

- Do not give Jevtana to a child or adolescent.

### 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.

**Some medicines may interfere with Jevtana and affect how it works. These include:**

- medicines used to treat bacterial, fungal or viral infections (e.g. clarithromycin, ketoconazole, rifampicin)
- medicines used to treat seizures or epilepsy (e.g. carbamazepine, phenobarbital, phenytoin)
- herbal remedy for depression and other conditions (St John's Wort (*Hypericum perforatum*))

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

## **4. How is Jevtana given?**

### **How much is given?**

- Jevtana will be given by infusion into one of your veins (intravenous use). The infusion will last approximately 1 hour during which you will be in the hospital.
- The dose will depend on your height and weight. Your doctor will calculate your body surface area in square meters (m<sup>2</sup>) and will determine the dose you should receive.
- The standard dose of Jevtana is 20 mg per square meter. Your doctor may decide on an alternative dose depending on your condition.
- Follow any instructions provided by your doctor.

### **Duration of treatment**

- You should usually receive your infusion once every 3 weeks.
- Each 3 week period is called one cycle of chemotherapy. Your doctor will decide how many of these cycles you will need.

## **Additional medications**

As part of your treatment for prostate cancer, you will also take an oral corticosteroid medicine (prednisone or prednisolone) daily.

Half an hour before you receive Jevtana, you will be given the following medications to reduce your chance of developing an allergic reaction or nausea:

- antihistamine (diphenhydramine or equivalent)
- corticosteroid (dexamethasone or equivalent)
- H2 antagonist (ranitidine or equivalent)
- anti-nausea medication (if required)

## **If you are given too much Jevtana**

As Jevtana is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any unexpected or worrying side effects after being given Jevtana, **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.**

If you receive too much Jevtana, you may experience one or more of the following symptoms: fever, nausea, diarrhoea, vomiting, constipation, abdominal pain, including upper abdominal pain, indigestion, and reflux.

## **5. What should I know while using Jevtana?**

### **Things you should do**

- Use a condom during sex if your partner is or could become pregnant.

Jevtana could be present in your semen and may affect the foetus. You are advised not to father a child during and up to 6 months after treatment and to seek advice on conservation of sperm prior to treatment because Jevtana may alter male fertility.

- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given this medicine.
- Talk to your doctor before getting vaccinations while you are receiving Jevtana.
- Keep all of your doctor's appointments so that your progress can be checked. If you do not complete the full course prescribed by your doctor, Jevtana may not work as well as it's supposed to.

### **Call your doctor straight away if:**

- your partner becomes pregnant while you are being given this medicine

Remind any doctor, dentist or pharmacist you visit that you are using Jevtana.

## **Driving or using machines**

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

Jevtana may cause side effects such as fatigue or dizziness that may affect your ability to drive and use machinery. Make sure you know how you react to Jevtana before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy or fatigued.

If you experience these symptoms, do not drive or use any tools or machines until they have fully resolved.

## **Looking after your medicine**

Jevtana is stored in the pharmacy or on the ward. Do not store at home.

## **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
<p data-bbox="204 432 459 477"><b>Gut-related</b></p> <ul data-bbox="204 510 762 1440" style="list-style-type: none"><li data-bbox="204 510 762 734">● stomach pain or upsets including nausea, vomiting and diarrhoea, constipation</li><li data-bbox="204 757 576 801">● abdominal pain</li><li data-bbox="204 824 762 981">● uncomfortable feeling in the stomach or belching after eating</li><li data-bbox="204 1003 576 1115">● loss of appetite (anorexia)</li><li data-bbox="204 1137 676 1249">● gastro-oesophageal reflux or heartburn</li><li data-bbox="204 1272 544 1317">● haemorrhoids</li><li data-bbox="204 1339 560 1384">● rectal bleeding</li><li data-bbox="204 1406 735 1440">● pain in mouth or throat</li></ul> <p data-bbox="204 1462 751 1507"><b>Nervous system-related</b></p> <ul data-bbox="204 1541 699 1921" style="list-style-type: none"><li data-bbox="204 1541 608 1585">● ringing in the ear</li><li data-bbox="204 1608 683 1653">● trouble with balance</li><li data-bbox="204 1675 448 1720">● dizziness</li><li data-bbox="204 1742 464 1787">● headache</li><li data-bbox="204 1809 699 1921">● alteration in sense of taste</li></ul>	<p data-bbox="817 432 1374 656"><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● feeling of numbness, tingling, burning or decreased sensations in hands and feet</li> </ul> <p><b>Blood-related</b></p> <ul style="list-style-type: none"> <li>● feeling tired, weak or lack of energy</li> <li>● symptoms of anaemia like tiredness, and inability to perform daily tasks (due to a decrease in the number of red blood cells)</li> <li>● blood in the urine</li> <li>● increased bleeding (due to a decrease in the number of platelets)</li> </ul> <p><b>Muscle and bone-related</b></p> <ul style="list-style-type: none"> <li>● back pain</li> <li>● joint pain</li> <li>● muscle spasm</li> <li>● muscle discomfort, aches or pain</li> <li>●</li> </ul>	

<b>Less serious side effects (cont)</b>	<b>What to do</b>
<p><b>Other reactions:</b></p> <ul style="list-style-type: none"> <li>● pain when passing urine</li> <li>● urinary incontinence</li> <li>● rapid or irregular heartbeat</li> <li>● redness of skin</li> <li>● skin feeling hot or flushed</li> <li>● swelling of the feet or legs</li> <li>● chills</li> <li>● shortness of breath</li> <li>● cough</li> <li>● short term hair loss (in most cases normal hair growth should return after treatment has stopped)</li> <li>● sores in the mouth or on the lips</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Allergic reaction-related:</b></p> <ul style="list-style-type: none"> <li>● swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing</li> <li>● hives</li> <li>● fainting</li> <li>● yellowing of the skin and eyes (jaundice)</li> <li>● skin rash</li> <li>● itching</li> <li>● shortness of breath</li> </ul> <p><b>Other reactions:</b></p> <ul style="list-style-type: none"> <li>● fever (high temperature). This is very common (affects more than 1 in 10 patients)</li> <li>● severe loss of body fluids (dehydration). This is common (affects less than 1 in 10 patients). This can occur if you have severe diarrhoea (increase of more than 4 or more stools more</li> </ul>	<p><b>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.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>than usual a day) or long-lasting diarrhoea, or fever, or if you are vomiting</p> <ul style="list-style-type: none"> <li>● urinary tract infection</li> <li>● fever and infection (associated with a reduction of white blood cells)</li> <li>● skin infections</li> <li>● lung infection</li> </ul>	

**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](http://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 Jevtana contains

<b>Active ingredient (main ingredient)</b>	Cabazitaxel  One ml of concentrate contains 40 mg cabazitaxel. Each vial of concentrate contains 60 mg cabazitaxel.
<b>Other ingredients (inactive ingredients)</b>	polysorbate 80  citric acid  ethanol 96%  water for injections
<b>Potential allergens</b>	ethanol 13% w/w

Jevtana does not contain gluten, sucrose, lactose, tartrazine or any other azo dyes.

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

## **What Jevtana looks like**

One pack of Jevtana consists of:

- One vial of 60 mg/1.5 mL concentrate (which is a clear yellow to brownish-yellow oily solution)
- One vial of 4.5 mL of 13% w/w ethanol in water for injections (which is a clear and colourless solution)

(Aust R 175500)

## **Who distributes Jevtana**

Jevtana is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

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