

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Jevtana.

It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given this medicine against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet in a safe place as you may need to read it again.

What Jevtana is used for

The name of your medicine is Jevtana. 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.

Ask your doctor if you have any questions about why it has been prescribed for you.

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

There is no evidence that this medicine is addictive.

Before you are given Jevtana

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 are pregnant or breast-feeding
- you have recently received or are about to receive a vaccine against yellow fever.

Do not receive Jevtana if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not receive Jevtana if you are pregnant or intend to become pregnant.

Jevtana may affect your developing baby if you are given Jevtana during pregnancy. If your partner is pregnant or is planning on becoming pregnant, ensure to use a condom.

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.

Do not receive Jevtana if you are breastfeeding or planning to breastfeed.

Jevtana could pass into breast milk and there is a possibility your baby may be affected.

Do not give Jevtana to a child or adolescent.

Do not receive Jevtana after the expiry date (EXP) printed on the vial.

If you receive it after the expiry date has passed, it may not work as well.

Do not receive Jevtana if the packaging is damaged or shows signs of tampering.

Before you are given Jevtana

Tell your doctor if:

- you have allergies to the ingredients listed at the end of this leaflet
- you are taking other medicines including medicines used to prevent blood clots and oral non-steroidal anti-inflammatories (NSAIDs).

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Jevtana is not recommended to be used during pregnancy. Your doctor will discuss the risks and benefits of receiving Jevtana if you are pregnant.

Tell your doctor if you are breastfeeding or planning to breastfeed.

It is not known whether Jevtana passes into breast milk. Your doctor will discuss the risks and benefits of receiving Jevtana if you are breastfeeding or planning to breastfeed.

Tell your doctor if you have or have had any medical conditions, especially the following:

- 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
- 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.
- if you have a feeling of numbness, tingling, burning or decreased sensation in your hands or feet
- if you have any bleeding from the gut that may cause changes in the colour of your stool or stomach pain.

This medicine contains 13% w/w ethanol (alcohol), equivalent to 14 ml of beer or 6 ml of wine. To be taken into account if:

- if suffer from alcoholism
- have a liver disease
- have epilepsy/seizures

Tell your doctor if you plan to have surgery.

If you have not already told your doctor about any of the above, tell them before you are given Jevtana.

Taking other medicines

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

This is because some medicines can affect the way Jevtana works or Jevtana can affect how other medicines work. 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))

Talk to your doctor before getting vaccinations while you are receiving Jevtana.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while being given Jevtana.

How Jevtana is given

How much to be given

The dose will depend on your height and weight. Your doctor will calculate your body surface area in square meters (m²) and will determine the dose you should receive.

The standard dose of Jevtana is 25mg per square metre. Your doctor may decide on an alternative dose depending on your condition.

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)

How Jevtana 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.

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.

If you have any further questions about how you will receive this medicine, ask your doctor, pharmacist or nurse.

If you receive too much (overdose)

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 immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or go to Accident and Emergency at your nearest hospital).

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.

While you are being given Jevtana

Things you must 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 fetus. 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 your partner becomes pregnant while you are being given this medicine, tell your doctor immediately.

Tell all the doctors, dentists and pharmacists who are treating you that you are being given Jevtana.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are being given Jevtana.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given this medicine.

Things you must not do

Do not receive more than the recommended dose unless your doctor tells you to.

Do not stop using Jevtana without checking with your doctor.

If you do not complete the full course prescribed by your doctor, Jevtana may not work as well as it's supposed to.

Things to be careful of

Be careful driving or operating machinery 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.

Side effects

Jevtana helps most people with prostate cancer, but it may have unwanted side effects in some people.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being given Jevtana.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

If any of the following happen while you are being given Jevtana in the hospital/clinic, Jevtana should be stopped immediately. Tell your doctor or nurse immediately. If you are outside of the

hospital/clinic go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- hives
- fainting
- yellowing of the skin and eyes (jaundice)

These are very serious side effects. If you have them, you may have had a serious allergic reaction to Jevtana. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

See a doctor immediately if you notice any of the following side effects:

- fever (high temperature). This is very common (affects more than 1 in 10 patients)
- 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 than usual a day) or long-lasting diarrhoea, or fever, or if you are vomiting

Tell your doctor, nurse or pharmacist if you notice any of the following:

Very common side effects (affects more than 1 in 10 patients):

- 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

Common side effects (affects less than 1 in 10 patients):

- urinary tract infection
- fever and infection (associated with a reduction of white blood cells)
- feeling of numbness, tingling, burning or decreased sensations in hands and feet
- dizziness
- headache
- decrease or increase in blood pressure
- uncomfortable feeling in the stomach or belching after eating
- gastro-oesophageal reflux or heartburn
- stomach pain
- haemorrhoids
- muscle spasm
- pain when passing urine
- urinary incontinence
- sores in the mouth or on the lips
- high blood sugar

- low blood potassium
- rapid or irregular heartbeat
- kidney disease or problems
- ringing in the ear
- trouble with balance
- blood clot in the leg
- pain in mouth or throat
- rectal bleeding
- redness of skin
- skin infections
- skin feeling hot or flushed
- muscle discomfort, aches or pain
- swelling of the feet or legs
- lung infection
- chills

Inflammation of the bladder may also occur if you have previously received radiation therapy. Tell your doctor, nurse or pharmacist if you have burning sensation when passing urine.

Tell your doctor, nurse or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Ask your doctor, nurse or pharmacist to answer any questions you may have if you experience any side effects.

After being given Jevtana

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor, nurse or pharmacist.

Storage

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

Product description

What Jevtana looks like

One pack of Jevtana consists of:

- One vial of 60mg/1.5ml concentrate (which is a clear yellow to brownish-yellow oily solution)
- One vial of 60mg/1.5ml diluent (which is a clear and colourless solution)

Ingredients

Active Ingredient:

The active substance is cabazitaxel. One ml of concentrate contains 40mg cabazitaxel. Each vial of concentrate contains 60mg cabazitaxel.

Inactive Ingredients:

The other ingredients are polysorbate 80 and citric acid in the concentrate and ethanol 96% and water for injections in the diluent.

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

Manufacturer/Sponsor

Jevtana is supplied in Australia by:

sanofi-aventis australia Pty Ltd
12-24 Talavera Road
Macquarie Park NSW 2113

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