

CABAZITAXEL EVER PHARMA®

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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I being given CABAZITAXEL EVER PHARMA?

CABAZITAXEL EVER PHARMA contains the active ingredient cabazitaxel. CABAZITAXEL EVER PHARMA is used to treat prostate cancer that has progressed after having had other chemotherapy.

For more information, see Section [1. Why am I taking CABAZITAXEL EVER PHARMA?](#) in the full CMI.

2. What should I know before I am given CABAZITAXEL EVER PHARMA?

Do not take CABAZITAXEL EVER PHARMA if you have ever had an allergic reaction to cabazitaxel or any of the ingredients listed at the end of this CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant, are breastfeeding or planning to breastfeed.

For more information, see Section [2. What should I know before I take CABAZITAXEL EVER PHARMA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CABAZITAXEL EVER PHARMA 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 will I be given CABAZITAXEL EVER PHARMA?

- CABAZITAXEL EVER PHARMA 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 (m²) and will determine the dose you should receive.

More instructions can be found in Section [4. How do I take CABAZITAXEL EVER PHARMA?](#) in the full CMI.

5. What should I know while taking CABAZITAXEL EVER PHARMA?

Things you should do	- Remind any doctor, surgeon, dentist or pharmacist you visit that you are using CABAZITAXEL EVER PHARMA. - Use a condom during sex if your partner is or could become pregnant.
Things you should not do	- Do not stop being given CABAZITAXEL EVER PHARMA without checking with your doctor. - Do not receive CABAZITAXEL EVER PHARMA if you are pregnant or breastfeeding. - Do not father a child during and up to 6 months after treatment.
Driving or using machines	Make sure you know how you react to CABAZITAXEL EVER PHARMA before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy or fatigued.
Drinking alcohol	Tell your doctor if you drink alcohol.
Looking after your medicine	CABAZITAXEL EVER PHARMA is stored in the pharmacy or on the ward. Do not store at home.

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

6. Are there any side effects?

Serious side effects include swelling of the face, lips, mouth or throat, hives, fainting, yellowing of the skin and eyes (jaundice). Common side effects include feeling weak or lack of energy, anaemia like tiredness, inability to perform daily tasks, increased bleeding, loss of appetite, alteration in sense of taste, shortness of breath.

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.

CABAZITAXEL EVER PHARMA®

Active ingredients: *cabazitaxel*

Consumer Medicine Information (CMI)

This leaflet provides important information about being given CABAZITAXEL EVER PHARMA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about being given CABAZITAXEL EVER PHARMA.**

Where to find information in this leaflet:

1. [Why am I taking CABAZITAXEL EVER PHARMA?](#)
2. [What should I know before I take CABAZITAXEL EVER PHARMA?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take CABAZITAXEL EVER PHARMA?](#)
5. [What should I know while taking CABAZITAXEL EVER PHARMA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given CABAZITAXEL EVER PHARMA?

CABAZITAXEL EVER PHARMA contains the active ingredient **cabazitaxel**. It belongs to a group of medicines called 'taxanes' used to treat cancers. CABAZITAXEL EVER PHARMA is used to treat prostate cancer that has progressed after having had other chemotherapy. It works by stopping cells from growing and multiplying.

There is no evidence that this medicine is addictive.

2. What should I know before I am given CABAZITAXEL EVER PHARMA?

Warnings

You must not be given CABAZITAXEL EVER PHARMA if:

- you are allergic to cabazitaxel 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.
- Always check the ingredients to make sure you can use this medicine.
- you have or have had any of the following medical conditions 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 pregnant or breast-feeding (see Pregnancy and Breastfeeding below)

Check with your doctor if you:

- have allergies to:
 - any other medicines
 - aspirin or any other non-steroidal anti-inflammatory drugs (NSAID)
 - any other substances, such as foods, preservatives or dyes
- have or have had any medical conditions, especially the following:
 - a fever (during treatment with CABAZITAXEL EVER PHARMA, 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
- take any medicines for any other condition
- plan to have surgery

The vial with 4.5 mL concentrate of CABAZITAXEL EVER PHARMA contains 888.8 mg ethanol 100% (25% v/v), equivalent to 22.5 mL of beer or 9.4 mL of wine. The vial with 5 mL concentrate of CABAZITAXEL EVER PHARMA contains 987.5 mg ethanol 100% (25% v/v), equivalent to 25 mL of beer or 10.4 mL of wine. The vial with 6 mL concentrate of CABAZITAXEL EVER PHARMA contains 1185 mg ethanol 100% (25% v/v), equivalent to 30 mL of beer or 12.5 mL of wine.

This will be taken into account if you:

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

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

Do not receive CABAZITAXEL EVER PHARMA if you are pregnant or intend to become pregnant.

CABAZITAXEL EVER PHARMA may affect your developing baby if you are given CABAZITAXEL EVER PHARMA 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. CABAZITAXEL EVER PHARMA might be present in your semen. Therefore, the use of a condom is always recommended during sexual intercourse.

Do not receive CABAZITAXEL EVER PHARMA if you are breastfeeding or planning to breastfeed.

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

Use in children

Do not give CABAZITAXEL EVER PHARMA 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 can interfere with CABAZITAXEL EVER PHARMA including:

- 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 CABAZITAXEL EVER PHARMA

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

4. How will I be given CABAZITAXEL EVER PHARMA?

How much will I 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 CABAZITAXEL EVER PHARMA is 20 mg per square metre. Your doctor may decide on an alternative dose depending on your condition.

How will I be given CABAZITAXEL EVER PHARMA

CABAZITAXEL EVER PHARMA 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 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 Medicines

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

If you receive too much CABAZITAXEL EVER PHARMA

As CABAZITAXEL EVER PHARMA 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 (such as fever, nausea, diarrhoea, vomiting, constipation, abdominal pain, including upper abdominal pain, indigestion, and reflux) after being given CABAZITAXEL EVER PHARMA

You should immediately:

- phone the Poisons Information Centre (in Australia by calling 13 11 26; in New Zealand 0800 764 766), 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.

5. What should I know while being given CABAZITAXEL EVER PHARMA?

Things you should do

- Use a condom while having sex if your partner is or could become pregnant.
- Tell the doctor immediately if your partner becomes pregnant while you are being given CABAZITAXEL EVER PHARMA.
- Seek advice on conservation of sperm prior to treatment because CABAZITAXEL EVER PHARMA may alter male fertility.
- Tell all the doctors, dentists and pharmacists who are treating you that you are being given CABAZITAXEL EVER PHARMA.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are being given CABAZITAXEL EVER PHARMA.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are being given this medicine.

Call your doctor straight away if you:

- have burning sensation when passing urine
- notice anything that is making you feel unwell

Things you should not do

- Do not father a child during and up to 6 months after treatment
- Do not receive more than the recommended dose unless your doctor tells you to
- Do not stop being given CABAZITAXEL EVER PHARMA without checking with your doctor

Driving or using machines

Be careful driving or operating machinery until you know how CABAZITAXEL EVER PHARMA affects you.

CABAZITAXEL EVER PHARMA 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 CABAZITAXEL EVER PHARMA 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.

Drinking alcohol

Tell your doctor if you drink alcohol or suffer from alcoholism

Looking after your medicine

CABAZITAXEL EVER PHARMA 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
Fatigue related: • 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) • dizziness Bleeding/blood related • increased bleeding (due to a decrease in the number of platelets) • blood clot in the leg • rectal bleeding • blood in the urine • haemorrhoids • decrease or increase in blood pressure • high blood sugar • low blood potassium Pain related • abdominal pain • muscle discomfort, aches or pain • back pain • joint pain • pain in mouth or throat • sores in the mouth or on the lips • stomach pain • pain when passing urine • headache • muscle spasm • feeling of numbness, tingling, burning or decreased sensations in hands and feet Infection related • fever and infection (associated with a reduction of white blood cells) • urinary tract infection • skin infections • lung infection Inflammation related • Inflammation of the bladder may also occur if you have previously received radiation therapy. • uncomfortable feeling in the stomach or belching after eating	Speak to your doctor if you have any of these less serious side effects and they worry you.

- gastro-oesophageal reflux or heartburn Allergy related - alteration in sense of taste - shortness of breath - redness of skin - skin feeling hot or flushed - swelling of the feet or legs - stomach upsets including nausea, vomiting and diarrhoea, constipation Other - loss of appetite (anorexia) - cough - short term hair loss (in most cases normal hair growth should return after treatment has stopped) - loss of bladder control - rapid or irregular heartbeat - kidney disease or problems - ringing in the ear - trouble with balance - chills	
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Serious side effects

Serious side effects	What to do
- 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.	See a doctor immediately

Very serious side effects

Serious side effects	What to do
- 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)	If you are in the hospital/clinic, tell your doctor or nurse immediately. If you are outside of the hospital/clinic go to Accident and Emergency at your nearest hospital.

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. 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 CABAZITAXEL EVER PHARMA contains

Active ingredients (main ingredient)	cabazitaxel
Other ingredients (inactive ingredients)	- polysorbate 80 - ethanol absolute - macrogol 300 - citric acid
Potential allergens	No

CABAZITAXEL EVER PHARMA does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

What CABAZITAXEL EVER PHARMA looks like

CABAZITAXEL EVER PHARMA concentrate is a clear slightly yellow oily solution.

CABAZITAXEL EVER PHARMA is available in packs of:

- one vial of 45 mg/4.5 mL
- one vial of 50 mg/5 mL
- one vial of 60 mg/6 mL

Australian Registration Number(s):

45 mg/4.5 mL

AUST R 320981

CABAZITAXEL EVER PHARMA

50 mg/5 mL

AUST R 320982

CABAZITAXEL EVER PHARMA

60 mg/6 mL

AUST R 321013

Who distributes CABAZITAXEL EVER PHARMA

InterPharma Pty Ltd

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Australia

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