Package leaflet: Information for the patient

Cabazitaxel 10 mg/ml Concentrate for Solution for Infusion

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cabazitaxel is and what it is used for

The name of your medicine is Cabazitaxel. Its common name is cabazitaxel. It belongs to a group of medicines called "taxanes" used to treat cancers.

Cabazitaxel is used to treat prostate cancer that has progressed after having had other chemotherapy. It works by stopping cells from growing and multiplying.

As part of your treatment, you will also take a corticosteroid medicine (prednisone or prednisolone) by mouth every day. Ask your doctor to give you information about this other medicine.

2. What you need to know before you are given Cabazitaxel

Do not use Cabazitaxel if:
- you are allergic to cabazitaxel, to other taxanes, or polysorbate 80 or any of the other ingredients of this medicine (listed in section 6).
- the number of your white blood cells is too low (neutrophil counts less than or equal to 1,500 /mm^3),
- you have severe abnormal liver function,
- you have recently received or are about to receive a vaccine against yellow fever.

You should not be given Cabazitaxel if any of the above apply to you. If you are not sure, talk to your doctor before having Cabazitaxel.

Warnings and precautions
Before each treatment with Cabazitaxel, you will have blood tests to check that you have enough blood cells and sufficient liver and kidney functions to receive Cabazitaxel.

Tell your doctor immediately if:
- you have fever. During treatment with Cabazitaxel, 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. He/she may give you other medicines to maintain the number of your blood cells. People with low blood counts can develop life-threatening infections. The earliest sign of infection may be fever, so if you experience fever, tell your doctor right away.
- you have ever had any allergies. Serious allergic reactions can occur during treatment with Cabazitaxel.

- you have severe or long-lasting diarrhoea, you feel sick (nausea) or you are being sick (vomiting). Any of these events could cause severe dehydration. Your doctor may need to treat you.
- you have feeling of numbness, tingling, burning or decreased sensation in your hands or feet.
- you have any bleeding problems from the gut or have changes in the colour of your stool or stomach pain. If the bleeding or pain is severe, your doctor will stop your treatment with Cabazitaxel. This is because Cabazitaxel may increase the risk of bleeding or developing holes in the gut wall.
- you have kidney problems.
- you have yellowing of the skin and eyes, darkening of the urine, severe nausea (feeling sick) or vomiting, as they could be signs or symptoms of liver problems.
- you experience any significant increase or decrease in daily urinary volume.
- you have blood in your urine.

If any of the above applies to you, tell your doctor immediately. Your doctor may reduce the dose of Cabazitaxel or stop the treatment.

Other medicines and Cabazitaxel
Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription. This is because some medicines can affect the way Cabazitaxel works or Cabazitaxel can affect how other medicines work. These medicines include the following:
- ketoconazole, rifampicin (for infections);
- carbamazepine, phenobarbital or phenytoin (for seizures);
- St John's Wort (*Hypericum perforatum*) (herbal remedy for depression and other conditions);
- statins (such as simvastatin, lovastatin, atorvastatin, rosuvastatin, or pravastatin) (for reducing the cholesterol in your blood);
- valsartan (for hypertension);
- repaglinide (for diabetes).

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

Pregnancy, breast-feeding and fertility
Cabazitaxel is not indicated for use in women.

Use a condom during sex if your partner is or could become pregnant. Cabazitaxel could be present in your semen and may affect the foetus. You are advised not to father a child during and up to 4 months after treatment and to seek advice on conservation of sperm prior to treatment because Cabazitaxel may alter male fertility.

Driving and using machines
You may feel tired or dizzy when having this medicine. If this happens, do not drive or use any tools or machines until you feel better.

Cabazitaxel contains ethanol (alcohol)
This medicinal product contains 1092 mg alcohol (ethanol) in each vial containing 6 ml concentrate which is equivalent to 23 vol%. The amount in 6 ml of this medicine is equivalent to 27.6 ml beer or 11.04 ml wine.

The small amount of alcohol in this medicine will not have any noticeable effects.

If you are addicted to alcohol, have liver disease or epilepsy talk to your doctor or pharmacist before taking this medicine.

3. How to use Cabazitaxel

Instructions for use
Anti-allergic medicines will be given to you before you have Cabazitaxel to reduce the risk of allergic reactions.

- Cabazitaxel will be given to you by a doctor <or a nurse>.
- Cabazitaxel must be prepared (diluted) before it is given. Practical information for handling and administration of Cabazitaxel for doctors, nurses and pharmacists is provided with this leaflet.
- Cabazitaxel will be given by a drip (infusion) into one of your veins (intravenous use) in hospital for about an hour.
- As part of your treatment, you will also take a corticosteroid medicine (prednisone or prednisolone) by mouth every day.

How much and how often to have
- The usual dose depends on your body surface area. Your doctor will calculate your body surface area in square meters (m^2) and will decide the dose you should have.
- You will usually have an infusion once every 3 weeks.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist <or nurse>.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the potential risks and benefits of your treatment.

See a doctor immediately if you notice any of the following side effects:
- fever (high temperature). This is common (may affect up to 1 in 10 people).
- severe loss of body fluids (dehydration). This is common (may affect up to 1 in 10 people). This can occur if you have severe or long-lasting diarrhoea, or fever, or if you are being sick (vomiting).
- severe stomach pain or stomach pain that doesn't go away. This can occur if you have a hole in the stomach, food pipe, gut or bowel (gastrointestinal perforation). This can lead to death.

If any of the above applies to you, tell your doctor immediately.

Other side effects include:

Very common (may affect more than 1 in 10 people):
- decrease in the number of red (anaemia), or white blood cells (which are important in fighting infection)
- decrease in the number of platelets (which results in increased risk of bleeding)
- loss of appetite (anorexia)
- stomach upsets including feeling sick (nausea), being sick (vomiting), diarrhoea or constipation
- back pain
- blood in the urine
- feeling tired, weak or lack of energy.

Common (may affect up to 1 in 10 people):
- alteration of taste
- shortness of breath
- cough
- abdominal pain
- short term hair loss (in most cases normal hair growth should return)
- joint pain

- urinary tract infection
- lack of white blood cells associated with fever and infection
- 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, heart burn or belching
- stomach pain
- haemorrhoids
- muscle spasm
- painful or frequent urination
- urinary incontinence
- kidney disease or problems
- sore in the mouth or on lips
- infections or risk of infections
- high blood sugar
- insomnia
- mental confusion
- feeling anxious
- abnormal feeling or loss of sensation or pain in hands and feet
- trouble with balance
- rapid or irregular heartbeat
- blood clot in the leg or in the lung
- skin feeling flushed
- pain in mouth or throat
- rectal bleeding
- muscle discomfort, aches, weakness or pain
- swelling of the feet or legs
- chills.
- nail disorder (change in the colour of your nails; nails may detach)

Uncommon (may affect up to 1 in 100 people):
- low blood potassium
- ringing in the ear
- skin feeling hot
- redness of the skin
- inflammation of the bladder, which can occur when your bladder has been previously exposed to radiation therapy (cystitis due to radiation recall phenomenon).

Frequency not known (cannot be estimated from the available data):
- interstitial lung disease (inflammation of the lungs causing coughing and difficulty breathing).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cabazitaxel

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton and on the label of the vial after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Information about storage and the time to use Cabazitaxel, once it has been diluted and is ready to use, are described in the section "PRACTICAL INFORMATION FOR MEDICAL OR HEALTHCARE PROFESSIONALS ON PREPARATION, ADMINISTRATION AND HANDLING OF Cabazitaxel".

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cabazitaxel contains
- The active substance is cabazitaxel. One ml of concentrate contains cabazitaxel 2-propanol solvate equivalent to 10 mg cabazitaxel. One vial of 6 ml concentrate contains cabazitaxel 2-propanol solvate equivalent to 60 mg cabazitaxel.
- The other ingredients are citric acid, anhydrous ethanol, polysorbate 80 and macrogol (see section 2 "Cabazitaxel contains ethanol (alcohol)").

What Cabazitaxel looks like and contents of the pack
Cabazitaxel concentrate for solution for infusion (sterile concentrate) is a clear, oily, light yellow solution.

Cabazitaxel is provided in a glass vial closed with bromobutyl rubber stopper sealed by an aluminium cap with polypropylene disk, containing 6 ml of concentrate. Vials may or may not be sheathed in a protective sleeve (a clear, colourless, protective film covering around the vial (sleeving) to provide additional safety measures).

Each pack contains 1 vial.

Marketing Authorisation Holder
Teva B.V.
Swensweg 5
2031 GA Haarlem
The Netherlands

Manufacturer
Pliva Croatia Ltd. Prilaz baruna Filipovica 25, 10000 Zagreb, Croatia HR

S.C. SINDAN-PHARMA S.R.L. 11th Ion Mihalache Blvd, 011171, Bucharest 1, Romania RO

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	Cabazitaxel TEVA 10 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Bulgaria	Кабазитаксел Тева 10 mg/ml концентрат за инфузионен разтвор Cabazitaxel Teva 10 mg/ml concentrate for solution for infusion
Czech Republic	Cabazitaxel Teva CR
Germany	Cabazitaxel-ratiopharm 10 mg/ml Konzentrat zur Herstellung einer

	Infusionslösung
Greece	Cabazitaxel/Teva
Denmark, Iceland, Norway	Cabazitaxel Teva B.V.
Spain	Cabazitaxel Tevagen 10 mg/ml concentrado para solución para perfusión
France	CABAZITAXEL TEVA PHARMA 10 mg/ml, solution à diluer pour perfusion
Croatia	Kabazitaksel Teva 10 mg/ml koncentrat za otopinu za infuziju
Hungary	Cabazitaxel Teva 10mg/ml koncentrátum oldatos infúzióhoz
Ireland	Cabazitaxel 10 mg/ml Concentrate for Solution for Infusion
Italy	Cabazitaxel Teva Italia
Netherlands	Cabazitaxel Teva 10 mg/ml, concentraat voor oplossing voor infusie
Portugal	Cabazitaxel Teva 10 mg/ml concentrado para solução para perfusão
Slovenia	Kabazitaksel Teva 10 mg/ml koncentrat za raztopino za infundiranje
Sweden	Cabazitaxel Teva B.V. 10 mg/ml koncentrat till infusionsvätska, lösning

This leaflet was last revised in October 2023.

The following information is intended for healthcare professionals only.

PRACTICAL INFORMATION FOR MEDICAL OR HEALTHCARE PROFESSIONALS ON PREPARATION, ADMINISTRATION AND HANDLING OF Cabazitaxel 10 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION

This information supplements sections 3 and 5 for the user.
It is important that you read the entire content of this procedure prior to the preparation of the infusion solution.

Incompatibilities

This medicinal product must not be mixed with other medicinal product except those used for the dilution.

Shelf life and special precautions for storage

Unopened vial
This medicinal product does not require any special storage conditions.

After first opening
The concentrate for solution for infusion must be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user. From a microbiological point of view, the dilution process must take place in controlled and aseptic conditions (see below "Preparation and administration precautions").

After dilution in the infusion bag/bottle
Chemical and physical in-use stability of the infusion solution has been demonstrated for 48 hours at 25°C (including the 1-hour infusion time) and for 72 hours at 2°C to 8°C (including the 1-hour infusion time).
From a microbiological point of view, the infusion solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Preparation and administration precautions

As for any other antineoplastic agent, caution should be exercised when handling and preparing Cabazitaxel solutions, taking into account the use of containment devices, personal protective equipment (e.g. gloves), and preparation procedures.
If Cabazitaxel, at any step of its handling, should come into contact with the skin, wash immediately and thoroughly with soap and water. If it should come into contact with mucous membranes, wash immediately and thoroughly with water.

<Product name> should only be prepared and administered by personnel trained in handling cytotoxic agents. Pregnant staff should not handle the medicinal product.

Preparation steps

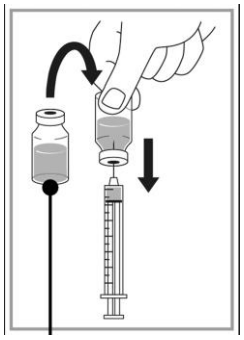
Read this **ENTIRE** section carefully before diluting. Cabazitaxel requires **ONE** dilution prior to administration. Follow the preparation instructions provided below.

The following dilution process must be carried out in an aseptic manner for preparing the solution for infusion.

More than one vial of the concentrate may be necessary to administer the prescribed dose.

Dilution for infusion

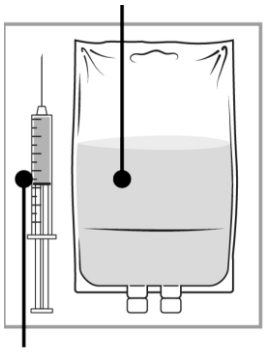
Step 1
Aseptically withdraw the required amount of concentrate (10 mg/ml of cabazitaxel), with a graduated syringe fitted with a needle. As an example, a dose of 45 mg <Product name> would require 4.5 ml of the concentrate.



Concentrate mixture 10 mg/ml

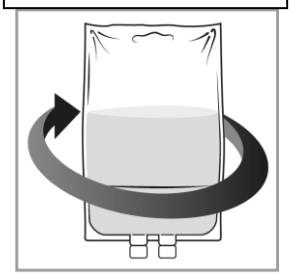
Step 2
Inject in a sterile PVC-free container of either 5% glucose solution or 0.9% sodium chloride solution for infusion. The concentration of the infusion solution should be between 0.10 mg/ml and 0.26 mg/ml.

5% glucose solution or sodium chloride 9 mg/ml (0.9%) solution for infusion



Required amount of concentrate mixture

Step 3
Remove the syringe and mix the content of the infusion bag or bottle manually using a rocking motion.



Step 4
As with all parenteral products, the resulting infusion solution should be visually inspected prior to use. As the infusion solution is supersaturated, it may crystallize over time. In this case, the solution must not be used and should be discarded.

The infusion solution should be used immediately. However, in-use storage time can be longer under specific conditions mentioned in section **Shelf life and special precautions for storage** above.

Each vial is for single use only.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Method of administration
Cabazitaxel is for intravenous use.
Cabazitaxel is administered as a 1 hour infusion.
An in-line filter of 0.22 micrometer nominal pore size (also referred to as 0.2 micrometer) is recommended during administration.
PVC infusion containers or polyurethane infusion sets should not be used for the preparation and administration of the infusion solution.