Cabazitaxel 20 mg/ml concentrate for solution for infusion
93054942409 GB

Cabazitaxel 20 mg/ml concentrate for solution for infusion
93054942409 GB

Package leaflet: Information for the patient

Cabazitaxel 20 mg/ml concentrate for solution for infusion

Read all of this leaflet carefully before you start taking 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. 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 take Cabazitaxel

Do not use Cabazitaxel if:

- you are allergic (hypersensitive) to cabazitaxel, to other taxanes, or polysorbate 80 or any of the other excipients 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

Please tell your doctor, pharmacist or nurse if you are taking or have recently taken 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 should not be used in pregnant women or women of childbearing age not using contraception.

Cabazitaxel should not be used during breast feeding.

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 alcohol (ethanol)

This medicine contains 50 vol % of alcohol (ethanol) in each dosage unit which is equivalent to 1,185 mg per vial. The amount in one dose of this medicine is equivalent to less than 30 ml beer or 12 ml wine.

This medicine may be harmful for those suffering from alcoholism.

To be taken into account if you are in a high-risk group such as patients with liver disease, or epilepsy.

3. How to take 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.

<u>The following information is intended for healthcare professionals only.</u>

Preparation Guide for use with Cabazitaxel 20 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.

Recommendations for the safe handling

Cabazitaxel is an antineoplastic agent and, as with other potentially toxic compounds, caution should be exercised when handling it and preparing its solutions. The use of gloves is recommended.

If Cabazitaxel concentrate or infusion solution should come into contact with skin, wash immediately and thoroughly with soap and water. If it should come into contact with mucous membranes, wash immediately and thoroughly with water.

Cabazitaxel should only be prepared and administered by personnel trained in handling cytotoxic agents. Pregnant staff should not handle it.

Incompatibilities

This medicine must not be mixed with other medicines except those used for the dilutions.

Shelf life and special precautions for storage

This medicinal product does not require any special storage conditions

After opening

The concentrate vials 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 two-step dilution process must take place in controlled and aseptic conditions (see below “Preparation and administration precautions”).

Preparation of the ready-to-use infusion solution

DO NOT use other cabazitaxel medicinal products consisting of 2 vials (concentrate and solvent) with Cabazitaxel 20 mg/ml concentrate for solution for infusion, which contains only 1 vial with 3 ml (60 mg/3 ml).

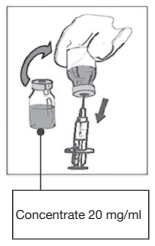
Cabazitaxel 20 mg/ml concentrate for solution for infusion requires NO prior dilution with a solvent and is ready to add to the infusion solution.

The whole content of the vial should not be used completely without proper control of volume, i.e. extract the exact volume required from the vial for dilution to adequately control the concentration.

Step 1:

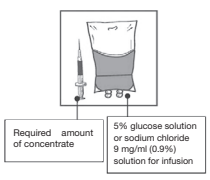
If the vials are stored under refrigeration, allow the required number of vials of cabazitaxel concentrate for solution for infusion to stand at 20–25 °C for 5 minutes before use.
More than one vial of cabazitaxel 20 mg/ml concentrate for solution for infusion may be necessary to obtain the required dose for the patient. Aseptically withdraw the required amount of cabazitaxel concentrate for solution for infusion using a calibrated syringe fitted with a 21G needle.

Each ml of the medicinal product contains 20 mg cabazitaxel.
As an example, a dose of 45 mg cabazitaxel would require 2.25 ml of cabazitaxel 20 mg/ml concentrate for solution for infusion.



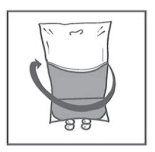
Step 2

The required volume of cabazitaxel concentrate for solution for infusion must be injected into a sterile PVC-free container of either 5 % glucose solution or 9 mg/ml (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.



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 crystallise over time. In this case, the solution must not be used and should be discarded.

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 (m2) 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.
- blood clot in the leg or in the lung. This is common (may affect up to 1 in 10 people).
- interstitial lung disease (inflammation of the lungs causing coughing and difficulty breathing). The frequency of this is unknown.

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
- skin feeling flushed
- pain in mouth or throat
- rectal bleeding
- muscle discomfort, aches, weakness or pain
- swelling of the feet or legs
- chills.

Uncommon *(may affect up to 1 in 100 people):*

- low blood potassium
- ringing in the ear
- skin feeling hot
- redness of the skin
- nail disorder (change in the colour of your nails; nails may detach)
- inflammation of the bladder, which can occur when your bladder has been previously exposed to radiation therapy (cystitis due to radiation recall phenomenon).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 vials 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 are described in the section “Preparation Guide for use with Cabazitaxel 20 mg/ml Concentrate for Solution for Infusion”.

Any unused 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 for solution for infusion contains 20 mg cabazitaxel. Each vial of concentrate for solution for infusion contains 60 mg of cabazitaxel.
The other ingredients are polysorbate 90, anhydrous ethanol (see section 2 “Cabazitaxel contains alcohol (ethanol)”, and citric acid.

What Cabazitaxel looks like and contents of the pack

Cabazitaxel is a concentrate for solution for infusion.

The concentrate is a clear yellow to brownish-yellow oily solution.

One vial contains 3 ml (nominal volume) concentrate. Pack sizes of one vial are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

STADA, Linthwaite, Huddersfield, HD7 5HQ, UK

Manufacturer

STADA Arzneimittel AG, Stadastr. 2-18, 61118 Bad Vilbel, Germany

Other formats

To request a copy of this leaflet in braille, large print or audio please call 01484 848164.

This leaflet was last revised in August 2024. 93054942409 GB

✂.....

Shelf-life

After opening of the vial

Chemical and physical in-use stability has been demonstrated for 4 weeks at 2 to 8 °C.

From a microbiological point of view, the product 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 to 8 °C.

Once added to the infusion bag

Chemical and physical in-use stability has been demonstrated in PVC-free infusion bags for 14 days at 2 to 8 °C and for 48 hours at 25 °C.

From a microbiological point of view, the product 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 to 8 °C, unless the dilution has taken place in controlled and validated aseptic conditions.

Disposal

All materials that have been utilised for dilution and administration should be disposed of according to standard procedures. Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

An in-line filter of 0.22 micrometre nominal pore size (also referred to as 0.2 micrometre) is recommended during administration.

Do not use PVC infusion containers or polyurethane infusion sets for the preparation and administration of cabazitaxel.

Cabazitaxel must not be mixed with any other medicinal products than those mentioned.

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

93054942409 GB