PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CABAZITAXEL ADCO 60 mg concentrate for solution for infusion

Cabazitaxel

Sugar free

Read all of this leaflet carefully before you are given CABAZITAXEL ADCO

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What CABAZITAXEL ADCO is and what it is used for

CABAZITAXEL ADCO is an anti-cancer medicine used with steroid medicines prednisone or prednisolone to treat men with prostate cancer that has worsened (progressed) after treatment with other medicines that included docetaxel.

2. What you need to know before you use CABAZITAXEL ADCO

CABAZITAXEL ADCO should not be administered to you:

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- If you are hypersensitive (allergic) to cabazitaxel or polysorbate 80 or any of the other ingredients of CABAZITAXEL ADCO (listed in section 6).
- You have neutrophil (white blood cell) counts of ≤ 1 500/mm3. Your doctor will be able to tell you if this is so.
- You have liver disease.
- You have recently received or are about to receive a vaccine against yellow fever.

Warnings and precautions

Special care should be taken with CABAZITAXEL ADCO:

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

Tell your doctor immediately if:

- You have fever. During treatment with CABAZITAXEL ADCO, 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 ADCO. Such reactions are characterised by shortness of breath, skin rash or very low blood pressure, and may develop within a few minutes of the start of the infusion. Your doctor may prescribe premedication to try and prevent this from happening. If you experience shortness of breath or a skin rash, please report such symptoms to your doctor immediately.

- You have severe or long lasting diarrhoea, nausea, vomiting, abdominal pain or constipation. Your doctor may give you medicines to treat these symptoms and prevent you from becoming dehydrated.

- 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 ADCO. This is because CABAZITAXEL ADCO may increase the risk of bleeding or developing holes in the gut wall.

- You have kidney problems or if you experience any significant increase or decrease in daily urinary volume or if you have blood in your urine.

- You have abnormal heart rhythms.

- You experience liver problems during the treatment.

- You have feeling of numbness, tingling, burning or decreased sensation in your hands or feet.

- You have shortness of breath or difficulty breathing. Immediately report new or worsening symptoms of the lung to your doctor.

- You have epilepsy or cannot take alcohol.

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

Children

The safety and the efficacy of CABAZITAXEL ADCO in children have not been established.

No data are available

Other medicines and CABAZITAXEL ADCO

Always tell your health care provider if you are taking any other medicine.

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(This includes complementary or traditional medicines.)

Some medicines can affect the way CABAZITAXEL ADCO works or CABAZITAXEL ADCO can affect how other medicines work. These medicines include the following:

- Ketoconazole, itraconazole or voriconazole for the treatment of fungal infections.
- Clarithromycin or telithromycin for the treatment of bacterial infections.
- Atazanavir, indinavir, nelfinavir, ritonavir or saquinavir for the treatment of HIV.
- Nefazodone for the treatment of anxiety or depression
- carbamazepine, phenobarbitone or phenytoin used for the treatment of seizures;
- rifampin, rifabutin and rifapentin used to treat TB (tuberculosis)
- St John's Wort (Hypericum perforatum), a herbal remedy for depression and other conditions.
- statins (such as simvastatin, lovastatin, atorvastatin, rosuvastatin, or pravastatin) used for reducing the cholesterol in your blood
- valsartan used to treat hypertension
- repaglinide used to treat diabetes

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

CABAZITAXEL ADCO should not be used in pregnant women or women of childbearing age not using contraception.

If you are a woman of childbearing potential, you must use an effective method of contraception before, during and up to 7 months after completion of treatment (i.e.: after the final dose) with CABAZITAXEL ADCO. If pregnancy occurs during your treatment with CABAZITAXEL ADCO you must immediately inform your doctor and should use genetic consultation.

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CABAZITAXEL ADCO should not be used during breast feeding.

Male fertility

If you are a man, you should avoid fathering a child during treatment with CABAZITAXEL ADCO and for up to 4 months after completion of treatment (i.e.: after the final dose). There is a risk that treatment with CABAZITAXEL ADCO will lead to infertility and you may wish to seek advice on conservation of sperm before treatment starts.

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.

It is not always possible to predict to what extent CABAZITAXEL ADCO may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which CABAZITAXEL ADCO affects you.

CABAZITAXEL ADCO contains ethanol (alcohol).

This medicine contains 13 % w/w ethanol (alcohol), equivalent to 14 ml of beer or 6 ml of 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 use CABAZITAXEL ADCO

- CABAZITAXEL ADCO will be administered by an intravenous (IV) infusion into your vein. You will not be expected to give yourself CABAZITAXEL ADCO. It will be given to you by a person who is qualified to do so.
- Caution should be exercised when handling and preparing CABAZITAXEL ADCO solutions. The use of gloves is recommended.

- If CABAZITAXEL ADCO at any step of its handling, should come into contact with the skin, wash

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immediately and thoroughly with soap and water. If it should come into contact with mucous membranes, wash immediately and thoroughly with water.

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

Preparation

Read this entire section carefully before mixing and diluting. CABAZITAXEL ADCO requires two dilutions prior to administration. Follow the preparation instructions provided below, as improper preparation may lead to overdose. Reconstitute the CABAZITAXEL ADCO vial using the entire contents of the diluent vial. Following this first dilution, the resultant solution contains a concentration of 10 mg/ml. Withdraw the exact volume required from the 10 mg/ml solution and dilute into 0,9 % sodium chloride or 5 % glucose solution to prepare the final infusion solution.

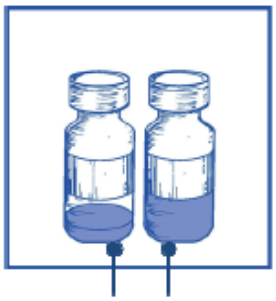
Note: Both the CABAZITAXEL ADCO injection and the diluent vials contain an overfill to compensate for liquid loss during preparation. This overfill ensures that after dilution with the entire contents of the accompanying diluent, there is an initial diluted solution containing 10 mg/ml CABAZITAXEL ADCO.

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

Step 1: Initial dilution of the concentrate for solution for infusion with the supplied solvent.

Step 1.1

Inspect the concentrate vial and the supplied solvent. The concentrate solution and the solvent should be clear.

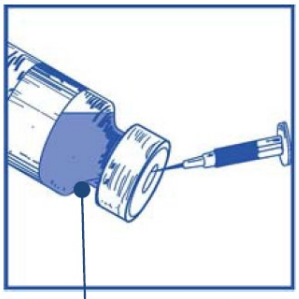


Concentrate vial (60 mg - 1.5 ml)

Solvent vial

Step 1.2

Using a syringe fitted with a needle, aseptically withdraw the **entire** contents of the supplied solvent by partially inverting the vial.

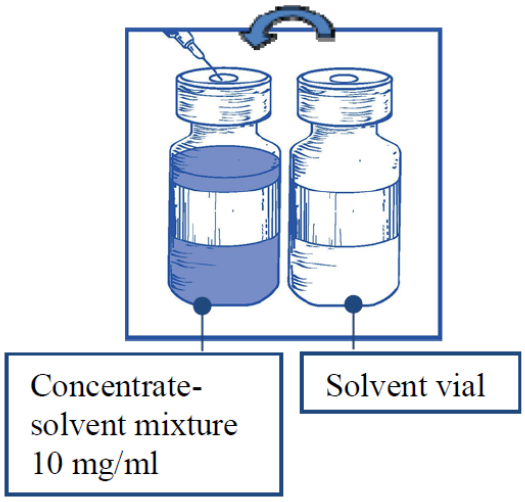


Solvent vial

Step 1.3

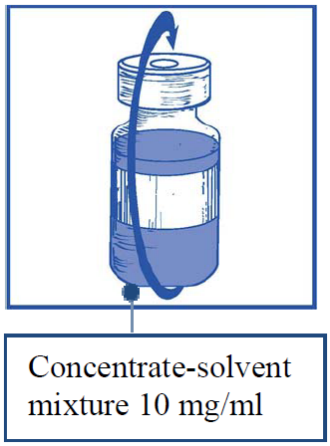
Inject the **entire** contents into the corresponding concentrate vial.

To limit foaming as much as possible when injecting the solvent, direct the needle onto the inside wall of the vial of concentrate solution and inject slowly. Once reconstituted, the resultant solution contains 10 mg/ml of cabazitaxel.



Step 1.4

Remove the syringe and needle and mix manually and gently by repeated inversions until obtaining a clear and homogeneous solution. It could take approximately 45 seconds.



Step 1.5

Let this solution stand for approximately 5 minutes and check then that the solution is homogeneous and clear. It is normal for foam to persist after this time period.

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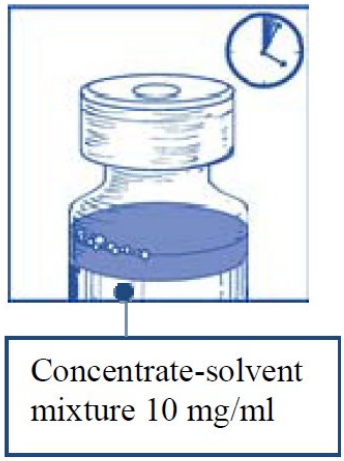


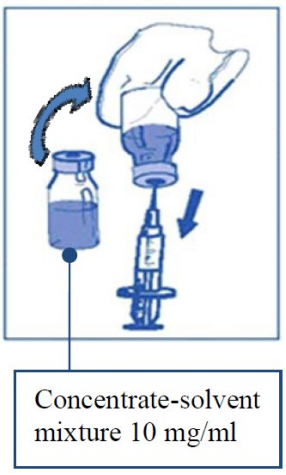
This resulting concentrate-solvent mixture contains 10 mg/ml of cabazitaxel (at least 6 ml deliverable volume). The second dilution should be done immediately (within 1 hour) as detailed in Step 2. More than one vial of the concentrate-solvent mixture may be necessary to administer the prescribed dose.

Step 2: Second (final) dilution for infusion

Step 2.1

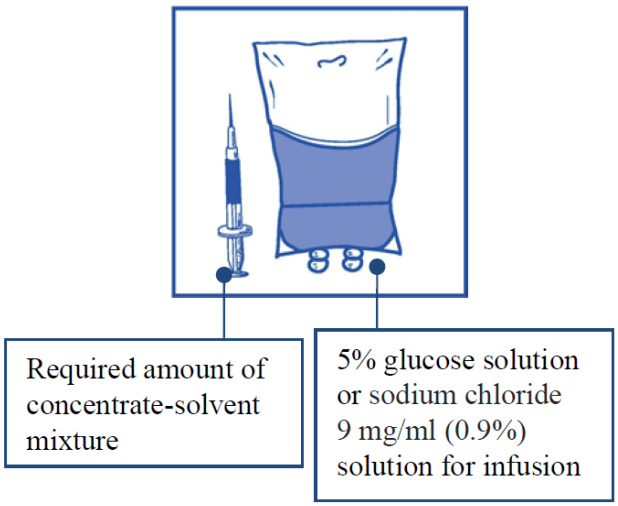
Aseptically withdraw the required amount of concentrate-solvent mixture (10 mg/ml of cabazitaxel), with a graduated syringe fitted with a needle. As an example, a dose of 45 mg CABAZITAXEL ADCO would require 4,5 ml of the concentrate-solvent mixture prepared following Step 1.

Since foam may persist on the wall of the vial of this solution, following its preparation described in Step 1, it is preferable to place the needle of the syringe in the middle when extracting.



Step 2.2

Inject in a sterile PVC-free container of either 5 % glucose solution or sodium chloride 9 mg/ml (0,9 %) solution for infusion. The concentration of the infusion solution should be between 0,10 mg/ml and 0,26 mg/ml.



Step 2.3

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

Step 2.4

The resulting infusion solution should be visually inspected prior to use. Solution containing a precipitate should be discarded.

Discard any unused portion.

- Your treatment will take about 1 hour.
- CABAZITAXEL ADCO is usually given every 3 weeks. Your healthcare provider will decide how often you will receive CABAZITAXEL ADCO.
- Your healthcare provider will also prescribe another medicine called prednisone for you to take by mouth every day during treatment with CABAZITAXEL ADCO. Your healthcare provider will tell you how and when to take your prednisone. It is important that you take prednisone exactly as prescribed by your healthcare provider. If you forget to take your prednisone, or do not take it on schedule, make sure to tell your healthcare provider or nurse.
- Before each infusion of CABAZITAXEL ADCO, you may receive other medicines to prevent or treat side effects.
- Your doctor will tell you how long your treatment with CABAZITAXEL ADCO will last. If you have the impression that the effect of CABAZITAXEL ADCO is too strong or too weak, tell your doctor or pharmacist.

IF YOU ARE GIVEN MORE CABAZITAXEL ADCO THAN YOU SHOULD:

Since a health care provider will administer CABAZITAXEL ADCO, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use CABAZITAXEL ADCO

Since a health care provider will administer CABAZITAXEL ADCO, it is unlikely that the dose will be missed.

4. Possible side effects

CABAZITAXEL ADCO can have side effects.

Not all side effects reported for CABAZITAXEL ADCO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CABAZITAXEL ADCO, please consult your health care provider for advice.

Severe allergic reactions can happen within a few minutes after your infusion of CABAZITAXEL ADCO starts, especially during the first and second infusions. Your healthcare provider should prescribe medicines before each infusion to help prevent severe allergic reactions.

If any of the following happens, stop receiving CABAZITAXEL ADCO and tell your doctor immediately.

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Skin rash or itching
- Itching and redness of your eyes
- Fainting
- Chest tightness or difficulty in breathing

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

Tell your doctor immediately if you notice any of the following:

- Decrease in number of white blood cells (which are important in fighting infection) resulting in infections.

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- Fever: if this happens you must tell your doctor immediately
- Low red blood cell count (anaemia): symptoms of anaemia include shortness of breath and tiredness.
- Low blood platelet count resulting in any unusual bruising or bleeding.
- Urinary tract infection resulting in burning urine and pain
- Kidney disease resulting in swelling of the face and body, decrease in the amount of urine that your body makes and blood in your urine.
- feeling of numbness or pins and needles or pain in the joints of muscles
- Vomiting and diarrhea: may lead to dehydration
- Severe stomach pain
- Blood in your stool or changes in the color of your stool
- Trouble breathing, cough, shortness of breath or chest pain

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- Decreased appetite and lack of taste or sores in the mouth
- Dizziness
- Headache
- Constipation
- Nausea
- Hair loss
- Back pain, bone pain or muscle pain
- Tiredness, lack of energy
- Decrease weight
- Haemorrhoids
- Muscle spasm
- High blood sugar

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- Low blood potassium
- Mental confusion
- Feeling anxious
- Ringing in the ear
- Trouble with balance
- Rapid or irregular heartbeat
- Blood clot in the leg
- Skin feeling hot or flushed
- Pain in mouth or throat
- Rectal bleeding
- Redness of the skin

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CABAZITAXEL ADCO.

For reporting of side effects directly to the HCR, contact +27 11 635 0134 or email Adcock.aereports@adcock.com

5. How to store CABAZITAXEL ADCO

Unopened: Store at or below 25 ºC. Keep in original container until required for use.

After reconstitution: Fully prepared CABAZITAXEL ADCO infusion solution (in either 0,9 % sodium chloride solution or 5 % glucose solution) should be used within 8 hours when stored between 15 °C

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and 25 °C (including the one-hour infusion), or for a total of 24 hours (including the one-hour infusion) under the refrigerated conditions at 2 to 8 ºC.

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 ºC, unless reconstitution has taken place in controlled and validated aseptic conditions.

For single use only, discard any unused portion.

6. Contents of the pack and other information

What CABAZITAXEL ADCO contains

CABAZITAXEL ADCO: Each single dose vial contains 60 mg cabazitaxel per 1,5 ml.

Diluent: Each vial contains 5,67 ml water for injection and ethanol 96 % (13 % w/w).

List of excipients:

Concentrate: Polysorbate 80

Diluent: Ethanol 96 %, water for injections

Sugar free

What CABAZITAXEL ADCO looks like and contents of the pack

CABAZITAXEL ADCO: Colourless to pale yellow viscous solution in a 15 ml clear USP Type-I tubular glass vial with a 20 mm grey chlorobutyl fluorotech coated rubber stopper and sealed with an aluminium seal having a polypropylene disc.

Diluent: Clear colourless solution in a 15 ml clear USP Type-I tubular glass vial with a 20 mm grey chlorobutyl fluorotech coated rubber stopper and sealed with an aluminium seal having a polypropylene disc.

Holder of Certificate of Registration

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