Package leaflet: Information for the patient

Cabazitaxel Fresenius Kabi 20 mg/ml concentrate for solution for infusion
cabazitaxel

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 Fresenius Kabi is and what it is used for

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

Cabazitaxel Fresenius Kabi 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 Fresenius Kabi

Do not use Cabazitaxel Fresenius Kabi 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 Fresenius Kabi if any of the above apply to you. If you are not sure, talk to your doctor before having Cabazitaxel Fresenius Kabi.

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

Tell your doctor immediately if:
- you have fever. During treatment with Cabazitaxel Fresenius Kabi, 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 Fresenius Kabi or stop the treatment.

Other medicines and Cabazitaxel Fresenius Kabi
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 Fresenius Kabi works or Cabazitaxel Fresenius Kabi 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 Fresenius Kabi.

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

Use a condom during sex if your partner is or could become pregnant. Cabazitaxel Fresenius Kabi 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 Fresenius Kabi 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 Fresenius Kabi contains ethanol (alcohol)
This medicine contains 395 mg of alcohol (ethanol) in 1 ml, which is equivalent to 39.5 % w/v. The amount in 2.25 ml of dose is equivalent to 23 mL of beer or 9 ml of 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.
Cabazitaxel Fresenius Kabi 20 mg/ml concentrate for solution for infusion contains polysorbate 80

This medicine contains 540mg of Polysorbate 80. Polysorbates may cause allergic reactions. Polysorbates can have an effect on your heart and blood circulation (e.g., irregular or abnormal heartbeat, or low blood pressure).

Tell your doctor if you have any known allergies.

3. How to use Cabazitaxel Fresenius Kabi

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

- Cabazitaxel Fresenius Kabi will be given to you by a doctor or a nurse.
- Cabazitaxel Fresenius Kabi must be prepared (diluted) before it is given. Practical information for handling and administration of Cabazitaxel Fresenius Kabi for doctors, nurses and pharmacists is provided with this leaflet.
- Cabazitaxel Fresenius Kabi 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

UK

Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

IE
HPRA Pharmacovigilance
Website: www.hpra.ie

5. How to store Cabazitaxel Fresenius Kabi

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 vials after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions

After opening
Each vial is for single use and should be used immediately after opening. If not used immediately, in- use storage times and conditions are the responsibility of the user.

After final dilution in the infusion bag/bottle

Chemical and physical stability of the infusion solution has been demonstrated for 8 hours at 15-30ºC (including the 1-hour infusion time) and for 48 hours at refrigerated conditions (including the 1-hour infusion time) in PVC free infusion containers.
From a microbiological point of view, the infusion solution should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2°C - 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Cabazitaxel Fresenius Kabi contains
The active substance is cabazitaxel. One ml of concentrate contains 20 mg cabazitaxel. Each 3 ml vial of concentrate contains 60 mg cabazitaxel.

The other ingredients are polysorbate 80, ethanol anhydrous and citric acid (see section 2 “Cabazitaxel Fresenius Kabi contains alcohol”).

What Cabazitaxel Fresenius Kabi looks like and contents of the pack
Cabazitaxel Fresenius Kabi is a concentrate for solution for infusion. The concentrate is a clear colourless to pale yellow solution.

It is supplied as a single-use vial with a deliverable volume of 3 ml concentrate in 6 ml clear glass vial.

Pack size:
Each carton contains one single use vial.

Marketing Authorisation Holder
Fresenius Kabi Deutschland GmbH
Else-Kröner-Straβe 1
61352 Bad Homburg v.d.H
Germany

Manufacturer
Fresenius Kabi Deutschland GmbH
Pfingstweide 53
61169 Friedberg
Germany

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Name of the Member State	Name of medicinal product
Austria	Cabazitaxel Fresenius Kabi 20 mg/ ml Konzentrat zur Herstellung einer Infusionslösung
Belgium	Cabazitaxel Fresenius Kabi 20 mg/ml, Concentraat voor oplossing voor infusie Cabazitaxel Fresenius Kabi 20 mg/ml, Solution à diluer pour perfusion Cabazitaxel Fresenius Kabi 20 mg/ml, Konzentrat zur Herstellung einer Infusionslösung
Bulgaria	Cabazitaxel Fresenius Kabi 20 mg/ml concentrate for solution for infusion Кабазитаксел Фрезениус Каби 20 mg/ml концентрат за инфузионен разтвор
Croatia	Kabazitaksel Fresenius Kabi 20 mg/ml koncentrat za otopinu za infuziju
Cyprus	Cabazitaxel Fresenius Kabi 20 mg/mL πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Czechia	Cabazitaxel Fresenius Kabi
Denmark	Cabazitaxel Fresenius Kabi
Estonia	Cabazitaxel Fresenius Kabi
Finland	Cabazitaxel Fresenius Kabi 20 mg/ml, infuusiokonsentraatti, liuosta varten
France	Cabazitaxel Fresenius Kabi 20 mg/mL, solution à diluer pour perfusion
Germany	Cabazitaxel Fresenius Kabi 20 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Greece	Cabazitaxel Fresenius Kabi 20 mg/mL πυκνό διάλυμα για παρασκευή διαλύματος προς έγχυση
Hungary	Cabazitaxel Fresenius Kabi 20 mg/ml koncentrátum oldatos infúzióhoz
Ireland	Cabazitaxel Fresenius Kabi 20 mg/ml concentrate for solution for infusion
Italy	Cabazitaxel Fresenius Kabi
Malta	Cabazitaxel Fresenius Kabi 20 mg/ml concentrate for solution for infusion
Latvia	Cabazitaxel Fresenius Kabi 20 mg/ml koncentrāts infūziju šķīduma pagatavošanai
Lithuania	Cabazitaxel Fresenius Kabi 20 mg/ml koncentratas infuziniam tirpalui
The Netherlands	Cabazitaxel Fresenius Kabi 20 mg/ml, Concentraat voor oplossing voor infusie
Norway	Cabazitaxel Fresenius Kabi
Poland	Cabazitaxel Fresenius Kabi
Portugal	Cabazitaxel Fresenius Kabi
Romania	Cabazitaxel Fresenius Kabi 20 mg/ml concentrat pentru soluție perfuzabil

Slovakia	Cabazitaxel Fresenius Kabi 20 mg/ml
Slovenia	Kabazitaksel Fresenius Kabi 20 mg/ml koncentrat za raztopino za infundiranje
Spain	Cabazitaxel Fresenius Kabi 20 mg/mL concentrado para solución para perfusión
Sweden	Cabazitaxel Fresenius Kabi 20 mg/ml koncentrat till infusionsvätska. lösning
United Kingdom (Northern Ireland)	Cabazitaxel Fresenius Kabi 20 mg/ml concentrate for solution for infusion

This leaflet was last revised in September 2025.

The following information is intended for healthcare professionals only.

PRACTICAL INFORMATION FOR MEDICAL OR HEALTHCARE PROFESSIONALS ON PREPARATION, ADMINISTRATION AND HANDLING OF CABAZITAXEL FRESENIUS KABI 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.

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

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

Shelf life and special precautions for storage

For the pack of Cabazitaxel Fresenius Kabi 20 mg/ml concentrate for solution for infusion
This medicinal product does not require any special storage conditions.

After opening
Each vial is for single use and should be used immediately after opening. If not used immediately, in-use storage times and conditions are the responsibility of the user.

After final dilution in the infusion bag/bottle
Chemical and physical stability of the infusion solution has been demonstrated for 8 hours at 15-30ºC (including the 1-hour infusion time) and for 48 hours at refrigerated conditions (including the 1-hour - infusion time) in PVC free infusion containers.

From a microbiological point of view, the infusion solution should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2°C - 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 Fresenius Kabi solutions, taking into account the use of containment devices, personal protective equipment (e.g., gloves), and preparation procedures.

If Cabazitaxel Fresenius Kabi, 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.

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

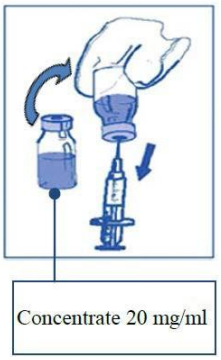
Preparation steps
DO NOT use together with other cabazitaxel medicinal products with a different concentration cabazitaxel. Cabazitaxel Fresenius Kabi contains 20 mg/ml of cabazitaxel (at least 3 ml deliverable volume).

Each vial is of single use and should be used immediately. Discard any unused solution.
More than one vial of Cabazitaxel Fresenius Kabi may be necessary to administer the prescribed dose.

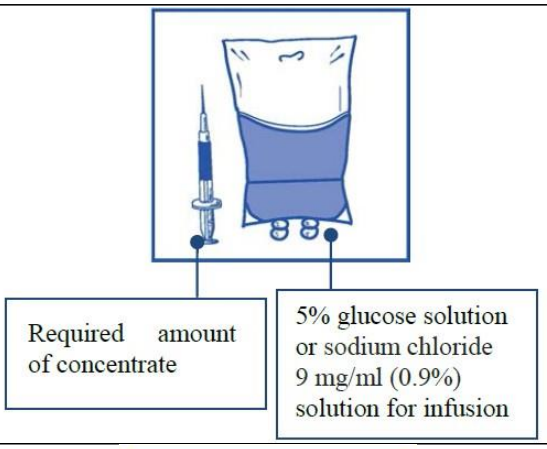
The dilution process must be carried out in an aseptic manner for preparing the solution for infusion.

Preparation of the infusion solution

Step 1
Aseptically withdraw the required volume of Cabazitaxel Fresenius Kabi (which contains 20 mg/ml of cabazitaxel), with a graduated syringe fitted with a needle. As an example, a dose of 45 mg cabazitaxel would require 2.25 ml of the Cabazitaxel Fresenius Kabi.



Step 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 3
Remove the syringe and mix the content of the infusion bag or bottle manually using a rocking motion. The infusion solution is clear colourless solution.

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. Information on **shelf life** and **special precautions for storage** are above.

Any remaining medicine and all the materials used for its reconstitution, dilution, and administration, must be destroyed following the hospital procedures applicable for cytotoxic agents and in compliance with current legislation relating to the elimination of hazardous materials waste.

Method of administration
Cabazitaxel Fresenius Kabi 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.