Package leaflet: Information for the patient

[Nationally approved name] 10 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 [Nationally approved name] is and what it is used for

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

[Nationally approved name] 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 [Nationally approved name]

Do not use [Nationally approved name] 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 [Nationally approved name] if any of the above apply to you. If you are not sure, talk to your doctor before having [Nationally approved name].

Warnings and precautions

Before each treatment with [Nationally approved name], you will have blood tests to check that you have enough blood cells and sufficient liver and kidney functions to receive [Nationally approved name].

Tell your doctor immediately if:

- you have fever. During treatment with [Nationally approved name], 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 [Nationally approved name].
- 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 [Nationally approved name]. This is because [Nationally approved name] 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 [Nationally approved name] or stop the treatment.

Other medicines and [Nationally approved name]

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 [Nationally approved name] works or [Nationally approved name] 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 [Nationally approved name].

Pregnancy, breast-feeding and fertility

[Nationally approved name] should not be used in pregnant women or women of childbearing age not using contraception.

[Nationally approved name] should not be used during breast-feeding.

Use a condom during sex if your partner is or could become pregnant. [Nationally approved name] could be present in your semen and may affect the foetus. You are advised not to father a child during and up to 6 months after treatment and to seek advice on conservation of sperm prior to treatment because [Nationally approved name] 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.

[Nationally approved name] contains ethanol (alcohol)

Vial 4.5 ml
This medicine contains 888.8 mg of alcohol (ethanol) in each vial. The amount of 4.5 ml in this medicine is equivalent to 22.5 ml beer or 9.4 ml wine.

Vial 5 ml
This medicine contains 987.5 mg of alcohol (ethanol) in each vial. The amount of 5 ml in this medicine is equivalent to 25 ml beer or 10.4 ml wine.

Vial 6 ml
This medicine contains 1185 mg of alcohol (ethanol) in each vial. The amount of 6 ml in this medicine is equivalent to 30 ml beer or 12.5 ml wine.

The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents.
The amount of alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

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

3. How to use [Nationally approved name]

Instructions for use

Anti-allergic medicines will be given to you before you have [Nationally approved name] to reduce the risk of allergic reactions.

- [Nationally approved name] will be given to you by a doctor <or a nurse>.
- [Nationally approved name] must be prepared (diluted) before it is given. Practical information for handling and administration of [Nationally approved name] for doctors, nurses and pharmacists is provided with this leaflet.

- [Nationally approved name] 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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store [Nationally approved name]

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.

Do not freeze.

Multi-dose vials: Chemical, physical and microbiological stability of the solution after first opening has been demonstrated for 28 days below 25°C. [Nationally approved name] is suitable for multi-dose use.

Information about storage and the time to use [Nationally approved name], 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 [Nationally approved name]".

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 to protect the environment.

6. Contents of the pack and other information

What [Nationally approved name] contains

The active substance is cabazitaxel. One ml of the concentrate for solution for infusion contains cabazitaxel monohydrate or anhydrous equivalent to 10 mg cabazitaxel.

Each vial of 4.5 ml of concentrate for solution for infusion contains cabazitaxel monohydrate or anhydrous equivalent to 45 mg cabazitaxel.

Each vial of 5 ml of concentrate for solution for infusion contains cabazitaxel monohydrate or anhydrous equivalent to 50 mg cabazitaxel.

Each vial of 6 ml of concentrate for solution for infusion contains cabazitaxel monohydrate or anhydrous equivalent to 60 mg cabazitaxel.

[Nationally approved name] 10 mg/ml concentrate for solution for infusion contains an overfill. This overfill ensures that there is extractable volume of 4.5 ml, 5 ml or 6 ml containing 10 mg/ml cabazitaxel.

The other ingredients are polysorbate 80; macrogol; citric acid; and ethanol, anhydrous (see section 2 "[Nationally approved name] contains alcohol").

What [Nationally approved name] looks like and contents of the pack

[Nationally approved name] is a concentrate for solution for infusion (sterile concentrate).

The concentrate is a clear slightly yellow oily solution.

One pack of [Nationally approved name] contains:

Clear glass vial closed with a grey bromobutyl rubber stopper sealed by an aluminium cap with a plastic flip-off cover containing 4.5 ml (5 ml or 6 ml) concentrate.

Vials may or may not be sheathed in a protective sleeve.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

EVER Pharma Jena GmbH
Otto-Schott-Str. 15
07745 Jena
Germany

EVER Pharma Jena GmbH
Brüsseler Str. 18
07747 Jena
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

<{Name of the Member State}><{Name of the medicinal product}>

This leaflet was last revised in 07/2023.

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

PRACTICAL INFORMATION FOR MEDICAL OR HEALTHCARE PROFESSIONALS ON PREPARATION, ADMINISTRATION AND HANDLING OF

[Nationally approved name] 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 medicine must not be mixed with other medicines except those used for the dilution.

Shelf life and special precautions for storage

This medicinal product does not require any special storage conditions.
Do not freeze.

<u>After first opening</u>

Multi-dose vials: Chemical, physical and microbiological stability of the solution after first opening has been demonstrated for 28 days below 25°C. [Nationally approved name] is suitable for multi-dose use.

After dilution in the infusion bag/bottle
Chemical and physical stability of the infusion solution has been demonstrated for 48 hours below 25°C including the 1-hour infusion time and for 14 days at refrigerated conditions 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 are the responsibility of the user and would normally not be longer than 24 hours below 25°C, unless dilution has taken place in controlled and validated aseptic conditions.

Preparation and administration precautions

[Nationally approved name] should only be prepared and administered by personnel trained in handling cytotoxic agents. Pregnant staff should not handle it.
As for any other antineoplastic agent, caution should be exercised when handling and preparing [Nationally approved name] solutions, taking into account the use of containment devices, personal protective equipment (e.g. gloves), and preparation procedures.
If [Nationally approved name], 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.

Preparation steps

Read this **ENTIRE** section carefully. [Nationally approved name] 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 [Nationally approved name] would require 4.5 ml of the concentrate.
[Nationally approved name] 10 mg/ml concentrate for solution for infusion contains an overfill. This overfill ensures that there is extractable volume of 4.5 ml, 5 ml or 6 ml containing 10 mg/ml cabazitaxel.

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.

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.

[Nationally approved name] 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.

Method of administration

[Nationally approved name] is administered as a 1-hour infusion.
PVC infusion containers or polyurethane infusion sets should not be used for the preparation and administration of the infusion solution.