Package leaflet: Information for the user
Carboplatine Venus 10 mg/ml concentraat voor oplossing voor infusie
Carboplatin

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. This includes any possible side effect not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Invented name> is and what it is used for

This medicine contains carboplatin, which belongs to a group of medicines known as platinum containing compounds, which are used to treat cancer.
This medicine is used in the treatment of small cell lung cancer and advanced ovarian cancer.

2. What you need to know before you are given <Invented name>

Do not have this medicine

- If you are allergic to Carboplatin or any of the other ingredients of this medicine (listed in section 6)
- If you have had hypersensitivity to similar platinum containing medicines in the past
- If you have severe kidney disease, unless it has been decided between you and your doctor that treatment is still the best option for you.

- if you have fewer blood cells than normal (your doctor will check this with a blood test)
- if you have tumor that bleeds
- if you plan to or have just received a yellow fever vaccination

Tell your doctor if any of the above apply to you before you are given this medicine.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given this medicine

- if you are trying to become pregnant or if there is a chance you may be pregnant
- if you are breast feeding
- if you have mild renal disease. Your doctor will want to monitor you more regularly
- if you are elderly (over 65 years old)
- if you have received treatment with a live vaccine (note that yellow fever vaccination is contraindicated)
- if you have been treated with cisplatin or similar anti-cancer medicines in the past, carboplatin may cause abnormalities in your nervous system, such as pins and needles or hearing and vision problems. Your doctor may regularly assess you.
- if you have headache, altered mental functioning, seizures and abnormal vision from blurriness to vision loss
- if you develop extreme tiredness and shortness of breath with decreased number of red blood cells (symptoms of haemolytic anaemia), alone or combined with low platelet count, abnormal bruising (thrombocytopenia) and kidney disease where you pass little or no urine (symptoms of Haemolytic-uraemic syndrome).
- if you have fever (temperature greater than or equal to 38°C), or chills, which could be signs of infection. You may be at risk of getting an infection of the blood.

In some cases, during treatment with carboplatin you will be given medicines which help reduce a potentially life- threatening complication known as tumour lysis syndrome, which is caused by chemical disturbances in the blood due to the breakdown of dying cancer cells that release their content to the bloodstream.

Other medicines and <Invented name>
Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Special care is needed if you are taking/ other medicines as some could interact with carboplatin, for example:

- medicines which can reduce the number of cells in your blood, may require changes to the dosage and frequency of your carboplatin treatment.
- some antibiotics called aminoglycosides, vancomycin or capreomycin, at the same time as carboplatin, may increase the risk of kidney or hearing problems.
- some water tablets (diuretics), at the same time as carboplatin, may increase the risk of kidney or hearing problems
- live or live-attenuated vaccines (for yellow fever vaccine see section 2, Do not use this medicine).
- blood thinning medicines e.g. warfarin, at the same time as carboplatin, may require an increase in frequency of blood coagulation monitoring.
- phenytoin and fosphenytoin (used to treat various types of convulsions and seizures) as carboplatin, may increase the risk of a seizure.
- other medicines which decrease the activity of the immune system (e.g. ciclosporin, tacrolimus, sirolimus).

This medicine with food and drink

There is no known interaction between Carboplatin and alcohol. However, you should check with your doctor as carboplatin may affect the liver's ability to cope with alcohol.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this medicine.

Pregnancy

Due to the possible risk of birth defects, carboplatin should not be used during pregnancy unless benefits of treatment for the mother are considered to outweigh the risk for the unborn child.

Women who can become pregnant are advised to avoid becoming pregnant during treatment with carboplatin (and for at least 7 months after the last dose) by using effective contraceptive measures.

Men are advised not to father a child during treatment with carboplatin (and during 4 months after the last dose) by using effective contraceptive measures.

Breast – feeding

Carboplatin is excreted in breast milk. Therefore, to avoid possible harmful effect in the infant, during treatment with carboplatin (and during 1 month after the last dose) breast-feeding must be discontinued.

Fertility

Treatment with carboplatin may cause (irreversible) infertility in both females and males. Prior to treatment with carboplatin you should therefore seek advice about the possibilities for preservation of fertility.

Driving and using machines

Do not drive or use machines if you experience any side effect which may lessen your ability such as nausea, vomiting, worsening of eyesight, or changes to your hearing.

3. How to use <Invented name>

This medicine will be given by infusion (drip) into a vein over 15-60 minutes.

Dose

Your doctor will work out the correct dose of carboplatin for you and how often it must be given.

The dose will depend on your medical condition, your size and how well your kidneys are working. Your doctor will tell how well your kidneys are working using blood or urine samples. You will have regular blood tests after your dose of carboplatin. You may also have checks for nerve damage and hearing loss. There is likely to be about 4 weeks between each dose of carboplatin.

If you receive more this medicine than you should

This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little However, tell your doctor or nurse if you have any concerns.

If you stop using this medicine
If you have any further question on the use of this product ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately:

- abnormal bruising, bleeding, or signs of infection such as a sore throat and high temperature (frequency very common, may affect more than 1 in 10 people).
- severe allergic reaction (anaphylaxis/anaphylactic reactions) - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint (frequency common, may affect up to 1 in 10 people).
- haemolytic-uraemic syndrome (a disease characterised by acute kidney failure), decreased urination or blood in the urine (frequency not known, cannot be estimated from the available data).
- muscle cramping, muscle weakness, confusion, visual loss or disturbances, irregular heartbeat, kidney failure or abnormal blood test results (these are symptoms of tumor lysis syndrome which can be caused by the rapid breakdown of tumor cells) (see section 2) (frequency not known, cannot be estimated from the available data).
- stroke (sudden numbness or weakness in the face, arm, or leg, especially on one side of the body) (frequency not known, cannot be estimated from the available data).
- obstruction in blood vessel (embolism and veno-occlusive disease), swelling or tenderness of leg/arm (frequency not known, cannot be estimated from the available data).
- chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome

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

Other side effect that may occur:

Very common (may affect more than 1 in 10 people)

- tiredness, shortness of breath and paleness caused by anaemia (a condition in which there is a decreased number of red blood cells)
- feeling sick (nausea) or being sick (vomiting)
- stomach pain and cramp
- decreased renal function

Tests may also show:

- changes in your red and white blood cells and platelets (myelosuppresion)
- increased in the level of urea in your blood
- decrease in the level of sodium, potassium, calcium and magnesium in your blood
- abnormal liver enzyme levels

Common (may affect up to 1 in 10 people)

- sign of infection such as fever or sore throat
- tingling or numbness in your hands, feet, arms or legs

- burning or prickling sensation
- decreased tendon reflex
- taste disturbance or loss of taste
- temporary worsening of eyesight or changes to your vision
- heart disorders
- tightness of the chest or wheezing
- interstitial lung disease (a group of lung disorders in which the deep lung tissues become inflamed)
- diarrhoea or constipation
- sore lips or mouth ulcers (mucous membrane disorders)
- hair loss
- rash and/or itchy skin
- pain or discomfort in your bones, joints, muscles, or surrounding structures (musculoskeletal disorder)
- problems with your kidneys or urine
- extreme tiredness/weakness (asthenia)

Tests may also show:
- increased level of bilirubin and creatinine in your blood
- increased level of uric acid in your blood which may lead to gout

Rare (may affect up to 1 in 1,000 people)
- temporary sight loss
- angioedema
- hyponatraemia
- loss of appetite, anorexia

Very rare (may affect up to 1 in 10,000 people)

- scarring of the lungs which causes shortness of breath and/or cough (pulmonary fibrosis)

Not known (frequency cannot be estimated from the available data)

- cancers caused by treatment with carboplatin (secondary malignancies)
- sore or inflammation inside of the mouth (stomatitis)
- a group of symptoms such as headache, altered mental functioning, seizures and abnormal vision (from blurriness to vision loss). These are symptoms of reversible posterior leukoencephalopathy syndrome, a rare neurological disorder
- dry mouth, tiredness, and headache due to excessive loss of body water (dehydration)
- pancreatitis
- severely impaired liver function, damage or death of liver cells
- heart failure
- skin disorders such as hives, rash, skin redness (erythema), and itching, in some cases very severe.
- swelling or soreness where the injection was given
- lung infection
- brain disorder (encephalopathy)
- anaemia due to abnormal breakdown of red blood cells (haemolytic anaemia)
- bone marrow failure
- ringing in the ears or changes in your hearing

- feeling unwell with high temperature due to low levels of white blood cells (febrile neutropenia)

Carboplatin may lead to problems with your blood, liver and kidneys. Your doctor will take blood samples to check for these problems.

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 to 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 <Invented name>

Keep this medicine out of the sight and reach of children

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

Do not refrigerate or freeze.
Keep vial in the outer carton in order to protect from light.

6. Contents of the pack and other information

What <Invented name> contains

The active substance is carboplatin.

Each 1 ml of concentrate for solution for infusion contains 10 mg carboplatin
Each vial of 15 ml of concentrate for solution for infusion contains 150 mg carboplatin
Each vial of 45 ml of concentrate for solution for infusion contains 450 mg carboplatin

Other ingredients is water for injections

What <Invented name> looks like and content of the pack
Concentrate for solution for infusion. <Invented name> is a clear, colourless to faintly yellow solution supplied in 20 ml and 50 ml type I moulded glass vial containing 15 ml and 45 ml concentrate for solution for infusion respectively. Vials are closed using omniflex rubber stoppers and sealed with aluminium flip off seals.

Pack size of 1 vial.

Not all presentations listed above may be marketed.

Marketing Authorization Holder and Manufacturer
Vergunninghouder:
Venus Pharma GmbH
Am Bahnhof 1-3
59368 Werne
Duitsland

Fabrikant:
European Pharma Hub Kft.
Gorcsev Ivan Utca 5

Gyal, 2360
Hongarije

In het register ingeschreven onder: RVG 132842

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

Netherland: Carboplatine Venus 10 mg/ml concentraat voor oplossing voor infusie
Hungary: Carboplatin Venus 10 mg/ml concentrate for solution for infusion
Romania: Carboplatin Venus 10 mg/ml concentrat pentru solutie perfuzabila
Croatia: Karboplatin Venus 10 mg/ml koncentrat za otopinu za infuziju
Slovenia: Karboplatin Venus 10 mg/ml koncentrat za raztopino za infundiranje

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2025.

The following information is intended for medical or healthcare professional only:

Instructions for use –Cytotoxic

The recommended dosage of Carboplatin in previously untreated adult patients with normal kidney function, i.e. creatinine clearance > 60 ml/min is 400 mg/m² as a single IV dose administered as a 15 to 60 minutes infusion. Alternatively, the Calvert formula shown below may be used to determine dosage:

Dose (mg) = target AUC (mg/ml x min) x [GFR ml/min + 25]

Target AUC	**Planned chemotherapy**	**Patient treatment status**
5-7mg/ml .min	single agent Carboplatin	Previously untreated
4-6mg/ml .min	single agent Carboplatin	Previously treated
4-6mg/ml .min	Carboplatin plus cyclophosphamide	Previously untreated

Note: With the Calvert formula, the total dose of Carboplatin is calculated in mg, not mg/m².

Therapy should not be repeated until four weeks after previous Carboplatin course and/or until the neutrophil count is at least 2,000 cells/mm³ and the platelet count is at least 100,000 cells/mm³.

Reduction of the initial dosage by 20-25% is recommended for those patients who present with risk factors such as prior myelosuppressive treatment and low performance status (ECOG-Zubrod 2-4 or Karnofsky below 80).

Determination of the haematological nadir by weekly blood counts during the initial courses of treatment with Carboplatin Infusion is recommended for future dosage adjustment.

Impaired renal function:
In patients with impaired renal function, dosage of carboplatin should be reduced (refer to Calvert formula) and haematological nadirs and renal function monitored.
Patients with creatinine clearance values of less than 60 ml/min are at greater risk to develop myelosuppression. The frequency of severe leukopenia, neutropenia, or thrombocytopenia has been maintained at about 25% with the following dosage recommendations:

Baseline Creatinine Clearance	Initial Dose (Day 1)
41-59 ml/min	250 mg/m^2 I.V.
16-40 ml/min	200 mg/m^2 I.V.

Insufficient data exist on the use of carboplatin injection in patients with creatinine of 15 ml/min or less to permit a recommendation for treatment.

Combination Therapy:
The optimal use of Carboplatin Infusion in combination with other myelosuppressive agents requires dosage adjustments according to the regimen and schedule to be adopted.

Paediatric patients:
The safety and efficacy of carboplatin in children has not yet been established. No data are available. As no sufficient experience of carboplatin use in children is available; no specific dosage recommendations can be given.

Elderly:
In the case of patients aged over 65, the carboplatin dosage needs to be adjusted to their general state of health during the first and subsequent courses of treatment.

Dilution :
The product must be diluted prior to infusion, with 5 % glucose solution or 0.9 % sodium chloride solution, to concentrations as low as 0.5 mg/ml.

Incompatibilities
Carboplatin may interact with aluminium to form a black precipitate. Needles, syringes, catheters or intravenous sets containing aluminium parts that may come into contact with carboplatin should not be used for preparation or administration of Carboplatin. Precipitation can lead to a reduction of the antineoplastic activity.

Shelf life
Unopened
2 years

After dilution
In use: Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature and 30 hours at 2-8°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 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.**Special precautions for storage**
Keep vial in the outer carton in order to protect from light.

INSTRUCTIONS FOR USE/HANDLING, PREPARATION AND DISPOSAL GUIDE FOR USE WITH CARBOPLATIN

Handling of Carboplatin

As with other antineoplastic agents, Carboplatin must be prepared and handled with caution.
The following protective measures should be taken when handling Carboplatin
Personnel should be trained in appropriate techniques for reconstitution and handling

1. Carboplatin should be prepared for administration only by professionals who have been trained in the safe use of chemotherapeutic agents. Personnel handling Carboplatin Infusion should wear protective clothing: goggles, gowns and disposable gloves and masks.
2. A designated area should be defined for syringe preparation (preferably under a laminar flow system), with the work surface protected by disposable, plastic-backed, absorbent paper
3. All items used for reconstitution, administration or cleaning (including gloves) should be placed in high- risk, waste-disposal bags for high temperature incineration.
4. Spillage or leakage should be treated with dilute sodium hypochlorite (1% available chlorine) solution, preferably by soaking, and then water. All contaminated and cleaning materials should be placed in high- risk, waste- disposal bags for incineration. Accidental contact with the skin or eyes should be treated immediately by copious lavage with water, or soap and water, or sodium bicarbonate solution. However, do not abrade the skin by using a scrub brush. Medical attention should be sought. Always wash hands after removing gloves.

Preparation of infusion solution
The product must be diluted before use. It may be diluted with 5% glucose solutioin or 0.9% sodium chloride solution, to concentrations as low as 0.5 mg/ml (500 micrograms/ml).

Disposal
This medicinal product is for single use only.
Medicines should not be disposed of via waste water or household waste. All material used for preparation, administration or otherwise coming into contact with carboplatin should undergo disposal according to local guidelines for the handling of cytotoxic compounds.