Package leaflet: Information for the user

Paclitaxin, concentraat voor oplossing voor infusie 6 mg/ml
paclitaxel

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
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

<Invented name> concentrate for solution for infusion is given only by healthcare personnel, who can reply to any questions which you may have after reading this package leaflet.

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

<Invented name>® is an antineoplastic or anticancer agent. It may stop cancer cells from dividing and growing.

<Invented name>® is used to treat different types of cancer, i.e.:

Ovarian cancer *(advanced or spreading ovarian cancer, residual tumour >1 cm after laparotomy)*
Either as initial therapy in combination with platinum-containing medicine, cisplatin, or as a second-line treatment when other platinum-containing treatments have not worked.

Breast cancer *(treatment of early breast cancer after surgical removal of the primary tumour, advanced or spreading breast cancer)*
As adjuvant therapy following treatment with anthracycline and cyclophosphamide (AC).
As initial therapy either in combination with a medicine belonging to the group known as anthracyclines in patients for whom anthracyclines therapy is suitable, or with a medicine called trastuzumab.
On its own in patients who have not responded to standard treatments using anthracyclines, or for whom such treatment should not be used.

A certain type of ***lung cancer*** *(Non-small cell lung cancer)*
In combination with cisplatin, in patients who are not candidates for potentially curative surgery and/or radiotherapy.

*It is also used to treat a special **AIDS-related form of cancer** that develops in the connective tissue (Kaposi's sarcoma)* where other treatments i.e. liposomal anthracyclines have not worked.

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

Do not use <Invented name>
- if you are allergic (hypersensitive) to paclitaxel or any of the other ingredients of this medicine (listed in section 6), especially macrogolglycerol ricinoleate
- if you are breast-feeding
- if your liver function is strongly reduced
- if your white blood cell count is too low (neutrophils). Your doctor will take blood samples to check this.
- if you have concurrent, serious, uncontrolled infections, and are being treated for Kaposi's sarcoma.

If any of these apply to you, **talk to your doctor before starting treatment with <Invented name>**.

Warnings and precautions
Talk to your doctor before you use <Invented name>

- if you experience severe allergic reactions (for example difficulty breathing, shortness of breath, chest tightness, drop in blood pressure, dizziness, lightheadedness, skin reactions such as rash or swelling).
- if you have fever, severe chills, sore throat or mouth ulcers (signs of bone marrow suppression); your physician will check your blood frequently.
- if you have a sore or red mouth (signs of mucositis) and are treated for Kaposi's Sarcoma. You may need a lower dose.
- if you experience heart problems during <Invented name> treatment; your physician should check the functioning of your heart before the next treatment with <Invented name>.
- if you have numbness, tingling, or weakness of the arms and legs (signs of peripheral neuropathy); a dose reduction of <Invented name> may be necessary.
- if you develop severe or persistent diarrhoea, with fever and stomach pain, during or shortly after the treatment with <Invented name>. Your colon could be inflamed (pseudomembranous colitis).
- if you had previous radiation to your chest (because it may increase the risk of lung inflammation).

You will be premedicated with several different medicinal products, belonging to the classes corticosteroids (for example dexamethasone), antihistamines (for example diphenhydramine or chlorphenamine) and H_2 antagonists (for example cimetidine or ranitidine) before every treatment with paclitaxel. Premedication is necessary to decrease the risk of severe hypersensitive reactions (see section 4. Possible side effects, uncommon).

Other medicines and <Invented name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because <Invented name> or the other medicines may not work as well as expected, or you may be more likely to get a side effect.

Interaction means that different medicines may influence each other. Speak to your doctor when using paclitaxel at the same time as any of the following:
- medicines for treating infections (i.e. antibiotics such as erythromycin, rifampicin, etc.: ask your doctor, nurse or pharmacist if you are unsure whether the medicine you are taking is an antibiotic), and including medicines for treating fungal infections (e.g. ketoconazole).
- medicines used to help you stabilize your mood also sometimes referred to as antidepressants (e.g. fluoxetine).
- medicines used to treat seizures (epilepsy) (e.g. carbamazepine, phenytoin).
- medicines used to help you lower blood lipid levels (e.g. gemfibrozil).
- medicines used for heartburn or stomach ulcers (e.g. cimetidine).
- medicines used to treat HIV and AIDS (e.g. ritonavir, saquinavir, indinavir, nelfinavir, efavirenz, nevirapine).
- a medicine called clopidogrel used to prevent blood clots.
- a medicine called rifampicin; an antibiotic used for tuberculosis. A dose increase of <Invented name> may be necessary.
- vaccines: If you have been vaccinated recently, or if you are planning to get vaccination, tell this to your doctor. The use of <Invented name> in combination with certain vaccines may lead to severe complications.
- cisplatin (to treat cancer): <Invented name> must be given before cisplatin. Your renal function may need to be checked more frequently.
- doxorubicin (to treat cancer): <Invented name> must be administered 24 hours after doxorubicin, to avoid high level of doxorubicin in your body.

If you are treated with a combination of Paclitaxel and doxorubicin or trastuzumab; your heart function will be checked both before and during treatment.

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 taking this medicine.

<Invented name> must not be used when you are pregnant, unless clearly necessary.
Paclitaxel may cause foetal harm. Avoid becoming pregnant and use effective contraceptives during therapy. If pregnancy occurs inform your doctor immediately. Female and male patients of fertile age, and/or their partners should use contraceptions for at least 6 months after treatment with <Invented name>.
Male patients should seek advice regarding cryoconservation of sperm prior to treatment with <Invented name> because of the possibility of infertility.

<Invented name> must not be used when you are breast-feeding. You have to interrupt breast-feeding while you are being treated with <Invented name>. Do not restart breast-feeding unless your doctor has allowed you to.

Driving and using machines
There is no reason why you cannot continue driving between courses of <Invented name> but you should remember that this medicine contains some alcohol and it may be unwise to drive immediately after a course of treatment. As in all cases, you should not drive if you feel dizzy or lightheaded.

Discuss with your doctor, nurse or pharmacist if you are unsure about anything.

<Invented name> contains alcohol and macrogolglycerol ricinoleate
A vial with paclitaxel contains 49.5 vol % alcohol (ethanol).
This medicine contains 2 g of alcohol (ethanol) in each 5 ml vial, 7 g in each 16.7 ml vial, 10 g in each 25 ml vial and 20 g in each 50 ml vial, which is equivalent to 396 mg/ml concentrate. The amount in one ml of this medicine is equivalent to 10 ml beer or 4 ml wine.

The amount of alcohol in this medicine can affect your ability to drive or use machines. This is because it may affect your judgement and how fast you react.

If you have epilepsy or liver problems, talk to your doctor or pharmacist before taking this medicine.

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

Because this medicine is usually given slowly over 3 or 24 hours, the effects of alcohol may be reduced.

Macrogolglycerol ricinoleate may cause severe allergic reactions.

3. How to use <Invented name>

To minimise allergic reactions, you will be given other medicines before you receive <Invented name>. These medicines can be given as either tablets or infusion into a vein or both.

Your doctor has decided which dose and how many doses you will be given. <Invented name> will be given under supervision of a doctor, who can give you more information.
The amount (dose) of <Invented name> you will be given is based on your body surface in square meters (m^2). This is calculated from your height and weight. The dose you receive will also depend on results of your blood tests.

Depending on the type and severity of the cancer you will receive <Invented name> either alone or in combination with another anticancer agent (e.g. cisplatin, doxorubicin, trastuzumab). <Invented name> is given into a vein (intravenous use) from an intravenous drip over 3 or 24 hours. <Invented name> is usually given every 3 weeks (2 weeks in patients with Kaposi's sarcoma), unless your doctor decides otherwise. Your doctor will inform you about the number of courses of <Invented name> you need to receive.
The needle must remain in the vein while the drug is being given. If the needle comes out or becomes loose, or the solution is going into the tissue outside the vein (you may feel discomfort or pain) – tell the doctor or nurse immediately.

Use in children

Paclitaxel is not recommended for use in children below 18 years due to lack of data on safety and effectiveness.

If you are given too much <Invented name>
There is no known antidote for <Invented name> overdose. You will receive treatment of your symptoms.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may occur amongst others:

Tell your doctor immediately if you notice any signs of allergic reactions. These may include one or more of the following:
- flushing,
- skin reactions,
- itching,
- chest tightness,
- shortness or difficulty in breathing,
- swelling.

These can all be signs of serious side effects.

Tell your doctor immediately
- if you have fever, severe chills, sore throat or mouth ulcers (signs of bone marrow suppression).
- if you have numbness or weakness of the arms and legs (signs of peripheral neuropathy).
- if you develop severe or persistent diarrhoea, with fever and stomach pain.

Very common (may affect more than 1 in 10 people)
- infections (mainly urinary tract and upper airways infections: inflammation of the nose mucous membrane characterized by a stuffed-up nose, sneezing and secretion (rhinitis) and inflammation of the throat (pharyngitis) and including herpes simplex, fungal infection of the mouth) (with reported cases of fatal outcome)
- deviations in blood content because of suppression of the bone marrow (myelosuppression)
- shortage of blood platelets causing bruises and tendency to bleed (thrombocytopenia)
- shortage of white blood cells attended with an increased sensitivity for infections (severe leucopenia, severe neutropenia), anaemia, bleeding
- mild hypersensitivity reactions (mainly flushing of the face and skin rash)
- anorexia
- neuropathy, mainly constant numbness, tingling or pain in hands and feet (all symptoms of peripheral neuropathy)*
- sleepiness
- paraesthesia
- lowered blood pressure

- nausea, vomiting, diarrhoea
- inflammation of the mucous membrane (mucositis)
- inflammation of the mucous membranes in the mouth (stomatitis), abdominal pain
- loss of hair (the majority of cases of hair loss happened less than one month after starting paclitaxel. When it happens, hair loss is pronounced (over 50%) in the majority of patients
- muscle pain and joint pain
- pain
- abnormal accumulation of fluid in hands, feet and face (oedema)

*Can persist beyond 6 months of paclitaxel discontinuation

Common: may affect up to 1 in 10 people

- flu syndrome
- blood disorder (shortage of white blood cells) accompanied with fever and increased sensitivity for infections (neutropenic fever)
- depression
- severe form of neuropathy, mainly resulting in constant numbness, tingling or pain in hands and feet (peripheral neuropathy), nervousness, sleeplessness, abnormal thinking, taste perversion, abnormal walking, movement disorder (hypokinesia), decreased sense of touch (hypoaesthesia)
- decreased heart rate (bradycardia), increased heart rate (tachycardia), palpitation
- loss of consciousness
- dilated blood vessel resulting in flushing
- bleeding nose
- dry mouth, mouth ulceration
- black and blood containing stools (melaena)
- indigestion
- dry skin, itch, acne, transient and mild nail and skin changes
- bone pain
- leg cramps, muscle weakness, back pain
- uncomfortable urination
- mild reaction at the place of injection (swelling of skin due to water retention (oedema), pain, redness (erythema), hardening of skin (induration), tenderness, skin discolouration or swelling, extravasation (leaking of drug outside the vein) which can result in cellulitis (painful swelling and redness), scar formation (skin fibrosis) and death of skin tissue (skin necrosis)). The onset of injection site reactions can be delayed by a week to 10 days.
- chest pain
- chills
- increase of certain enzymes in the blood (AST, SGOT).

Uncommon: may affect up to 1 in 100 people

- severe infection
- serious lowering of the blood pressure by bacteria in the blood accompanied with paleness and restlessness, high heart rate and moist skin (septic shock)
- severe anaemia
- (delayed) hypersensitivity

- serious hypersensitivity reactions (angioedema) which make treatment necessary (e.g. low or high blood pressure, swelling of the face, tongue or lips, breathing problems or general rash, chills, back pain, chest pain, fast heart rhythm, stomach pain, pain in the hands and feet, sweating)
- weight loss, weight gain
- dry eyes, lazy eye (amblyopia)
- vision field disorder
- myocardial infarction
- insufficient pump function of the heart (congestive heart failure)
- disorders of the heart muscle (cardiomyopathy)
- disorders in the heart rhythm (fast heartbeat: asymptomatic ventricular tachycardia, tachycardia with bigeminia)
- disturbance in the heart conductance (AV block) sometimes with loss of consciousness
- disorders of the electrocardiogram
- high blood pressure
- thrombosis, inflammation of the veins with the formation of a blood clot, which can often be felt as a painful, harsh strand with a red skin
- discoloration of the nails or nail beds
- severe increase in bilirubin (jaundice).

Rare: may affect up to 1 in 1,000 people

- severe blood poisoning (sepsis)
- inflammation of the lungs (pneumonia)
- inflammation of the abdominal membrane (peritonitis)
- fever associated with a low number of specific white blood cells which are needed to fight an infection (febrile neutropenia)
- serious general and possibly life-threatening hypersensitivity reactions (anaphylactic reactions)
- affection of movement nerves causing muscle weakness of arms and feet (motor neuropathy)
- heart failure
- shortness of breath
- pleural effusion, pneumonia (interstitial pneumonia)
- lung fibrosis, airway occlusion (pulmonary embolism), breathing difficulties
- pain in the stomach for instance caused by constipation or a hole in the intestine (intestinal obstruction/perforation)
- inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis)
- inflammation of the large intestine with possible serious continuous diarrhoea (ischaemic colitis)
- redness of the skin
- skin rash, heavily itching rash (pruritus)
- fever
- loss of body fluids (dehydration)
- water retention (oedema)
- weakness, general discomfort
- increase in blood creatinine

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

- sudden disorders of blood forming bone marrow cells (acute myeloid leukaemia, myelodysplastic syndrome)
- serious, general and possibly life-threatening hypersensitivity reactions with shock
- confusion, defect of certain nerves (autonomous neuropathy) which could result in paralysis of the intestine muscles (paralytic ileus) and a
- sudden drop in blood pressure sometimes with dizziness caused by, for instance, fast rising from a seated or lying position (orthostatic hypotension)
- (epileptic) fits, affection of the brain characterised by, for instance, convulsions and lowering of the consciousness (encephalopathy), coordination disturbances (ataxia)
- headache
- dizziness
- disorders of the eye nerve and/or disorder of the vision (scotoma scintillans)
- damage to the ears (ototoxicity), hearing loss, dizziness (vertigo)
- ringing in the ears (tinnitus)
- irregular fast heart-beat (atrial fibrillation)
- faster heart-beat originating from a specific part of the heart (supraventricular tachycardia)
- shock
- cough
- high blood pressure in the lungs
- inflammation of the large intestine with possible serious continuous diarrhoea (neutropenic colitis, pseudomembranous colitis, necrotising colitis)
- blood clot in the abdominal membrane (mesenteric thrombosis)
- inflammation of the gullet (oesophagitis)
- accumulation of fluid in the abdominal cavity (ascites)
- constipation
- disturbed functioning of the liver (hepatic necrosis, hepatic encephalopathy) with reported cases of fatal outcome
- serious hypersensitivity reaction with fever, red spots on the skin, joint pain and/or inflammation of the eye (Stevens-Johnson syndrome)
- local necrosis of the skin (epidermal necrolysis), rash with red (moist) irregular spots (erythema multiforme), nettle rash and formation of bumps (urticaria)
- losing nails (patients in therapy should wear sun protection on hands and feet)
- inflammation of hair follicles (folliculitis)
- inflammation of the skin with blisters or peeling (exfoliative dermatitis)

Not known (frequency cannot be determined based on the available data)

- complications caused by the break-down products of dying cancer cells (tumour lysis syndrome)
- fluid accumulation in the eye (macular oedema), light flashes in the eye (photopsia), little dots or dust floating in your field of vision (vitrious floaters), increased tear secretion
- inflammation of a vein (phlebitis)
- excessive deposits of collagen in the skin (scleroderma)

- autoimmune disease with multiple symptoms, such as red and squamous patches on the skin, pain in the joints or fatigue (systemic lupus erythematosus) or red, thick, and often scaly rashes and sores that may burn or itch (cutaneous lupus erythematosus)
- redness and swelling of the palms of your hands or soles of your feet which may cause your skin to peel.
- disseminated intravascular coagulation, or "DIC" has been reported. This concerns a serious condition that makes people bleed to easily, get blood clots too easily, or both.
- acute inflammatory reaction confined to previously irradiated areas that is triggered by the administration of precipitating systemic agents after radiation treatment (recall phenomenon)
- excessive sweating (hyperhidrosis)

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 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 the expiry date which is stated on the vial and the outer carton after "do not use after "or "EXP". The first 2 numbers indicate the month, the last numbers indicate the year. The expiry date refers to the last day of the month.

No special storage temperature, store in the original carton.
Freezing does not have harmful effects on the product.

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 <Invented name> contains
- The active substance is paclitaxel.
  <Invented name>, concentrate for solution for infusion contains 6 mg paclitaxel per ml.
- The other ingredients are macrogolglycerol ricinoleate; ethanol, anhydrous and citric acid.

What <Invented name> looks like and contents of the pack
<Invented name> is a clear, colourless or slightly yellow, viscous solution. It is available in vials with 5 ml, 16.7 ml, 25 ml and 50 ml.
Each 5 ml vial contains 30 mg paclitaxel.
Each 16.7 ml vial contains 100 mg paclitaxel.
Each 25 ml vial contains 150 mg paclitaxel.
Each 50 ml vial contains 300 mg paclitaxel.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Pharmachemie B.V.
Swensweg 5
2031 GA Haarlem
Nederland

Manufacturer
Pharmachemie B.V.
Swensweg 5
P.O. Box 552,
2003 RN Haarlem
Nederland

In het register ingeschreven onder:
RVG 30113

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

België	Paclitaxin 6 mg/ml concentraat voor oplossing voor infusie (30 mg/5 ml) Paclitaxin 6 mg/ml concentraat voor oplossing voor infusie (100 mg/16,7 ml) Paclitaxin 6 mg/ml concentraat voor oplossing voor infusie (150 mg/25 ml) Paclitaxin 6 mg/ml concentraat voor oplossing voor infusie (300 mg/50 ml)
Estland	Paclitaxel-Teva
Frankrijk	Paclitaxel-Teva 6 mg/ml solution à diluer pour perfusion
Duitsland	Paclitaxel-GRY® 6 mg/ml Konzentrat zur Herstellung einer Infusionslösung
Griekenland	Paxene Paclitaxin
Hongarije	Paclitaxel-Teva 6 mg/ml koncentrátum oldatos infuzióhoz
Italië	Paclitaxel Teva 6 mg/ml soluzione concentrata per infusione
Litouwen	Paclitaxel-Teva 6 mg/ml koncentratas infuziniam tirpalui
Luxemburg	Paclitaxin 6 mg/ml solution à diluer pour perfusion (30 mg/5 ml) Paclitaxin 6 mg/ml solution à diluer pour perfusion (100 mg/16,7 ml) Paclitaxin 6 mg/ml solution à diluer pour perfusion (150 mg/25 ml) Paclitaxin 6 mg/ml solution à diluer pour perfusion (300 mg/50 ml)
Nederland	Paclitaxin, concentraat voor intraveneuze oplossing 6 mg/ml
Slovenië	Paclitaxin 6 mg/ml, koncentrat za raztopino za infundiranje
Spanje	Paclitaxel Teva 6 mg/ml, concentrado para solución para perfusión

Deze bijsluiter is voor het laatst goedgekeurd in november 2024.

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

Below is a summary of information to assist in the administration of <Invented name>. You should be experienced in the handling and use of cytotoxic agents and be familiar with the SPC of <Invented name>. Reference should be made to guidelines on the safe handling of antineoplastic agents.

Handling: as with all antineoplastic agents, caution should be exercised when handling <Invented name>. Pregnant women should not handle cytotoxic agents. Dilution should be carried out under aseptic conditions by trained personnel in a designated area. Adequate protective gloves should be worn. Precautions should be taken to avoid contact with the skin or mucous membranes. In the event of contact with the skin, the area should be washed with soap and water. Following topical exposure, tingling, burns and redness have been observed. In the event of contact with the mucous membranes, these should be flushed thoroughly with water. Upon inhalation, dyspnoea, chest pain, burning throat and nausea have been reported.

If unopened vials are refrigerated or frozen, a precipitation may form, that redissolves with little or no agitation upon reaching room temperature. Product quality is not affected. If the solution remains cloudy or if an insoluble precipitate is noted, the vial should be discarded.

Following multiple needle entries and product withdrawals, the vials maintain microbial, chemical and physical stability for up to 28 days at 25°C. Other in-use storage times and conditions are the responsibility of the user.

The 'Chemo-Dispensing Pin' device or similar devices with spikes should not be used since they can cause the vial stopper to collapse, resulting in loss of sterile integrity.

Preparation for intravenous administration: prior to infusion, <Invented name> must be diluted using aseptic techniques in 9 mg/ml (0.9%) sodium chloride solution for infusion, or 50 mg/ml (5%) glucose solution for infusion, or a mixture of 9 mg/ml (0.9%) sodium chloride solution for infusion and 50 mg/ml (5%) glucose solution for infusion**,** or Ringer's solution for infusion containing 50 mg/ml (5%) glucose, to a final concentration of 0.3 to 1.2 mg/ml.

Chemical and physical in-use stability of the solution prepared for infusion has been demonstrated for 27 hours at 25°C when diluted in a mixture of 9 mg/ml (0.9%) sodium chloride solution for infusion and 50 mg/ml (5%) glucose solution for infusion, or Ringer's solution for infusion containing 50 mg/ml (5%) glucose.
Chemical and physical in-use stability of the solution prepared for infusion has been demonstrated at 5°C and at 25°C for 14 days when diluted in 50 mg/ml (5%) glucose solution for infusion or in 9 mg/ml (0.9%) sodium chloride solution for infusion.
Microbiological in-use stability of the solution prepared for infusion has been demonstrated for 27 hours at 25°C. Other in-use storage times and conditions are the responsibility of the user.

Upon preparation, solutions may show some haziness, which is attributed to the formulation vehicle, and is not removed by filtration. <Invented name> should be administered through an in-line filter with a microporous membrane ≤ 0.22 µm. No significant losses in potency have been noted following simulated delivery of the solution through IV tubing containing an in-line filter.

There have been rare reports of precipitation during paclitaxel infusions, usually towards the end of a 24-hour infusion period. Although the cause of this precipitation has not been

elucidated, it is probably linked to the supersaturation of the diluted solution. To reduce the precipitation risk, <Invented name> should be used as soon as possible after dilution, and excessive agitation, vibration or shaking should be avoided. The infusion sets should be flushed thoroughly before use. During infusion, the appearance of the solution should be regularly inspected and the infusion should be stopped if precipitation is present.

To minimise patient exposure to DEHP [di-(2-ethylhexyl)phthalate] which may be leached from plasticised PVC infusion materials, diluted paclitaxel solutions should be stored in non-PVC bottles (glass, polypropylene) or plastic bags (polypropylene, polyolefin) and administered through polyethylene-lined administration sets. Use of filter devices which incorporate short inlet and/or outlet plasticised PVC tubing has not resulted in significant leaching of DEHP.

Disposal: all items used for the preparation, administration or otherwise coming into contact with <Invented name> should undergo disposal according to local guidelines for the handling of cytotoxic compounds.

Administration and dosage
All patients should be premedicated with corticosteroids, antihistamines and H_2 antagonists prior to administration. The diluted <Invented name> infusion should be administrated using non-PVC containing equipment through an in-line filter with a microporous membrane ≤ 0.22 µm.

The recommended doses for the intravenous infusion of <Invented name> are as follows:

First-line ovarian cancer:	135 mg/m^2 over 24 hours, followed by cisplatin 75 mg/m^2; or 175 mg/m^2 over 3 hours, followed by cisplatin 75 mg/m^2;
Second-line ovarian or breast cancer:	175 mg/m^2 over 3 hours;
Adjuvant breast cancer:	175 mg/m^2 over 3 hours; following anthracycline and cyclophosphamide (AC) therapy;
First-line breast cancer:	220 mg/m^2 over 3 hours, 24 hours after doxorubicin (50 mg/m^2), 175 mg/m^2 over 3 hours, after trastuzumab (see trastuzumab SPC);
Non-small cell lung cancer:	175 mg/m^2 over 3 hours, followed by cisplatin 80 mg/m^2:
AIDs related Kaposi's sarcoma:	100 mg/m^2 over 3 hours.

Storage
There are no special storage conditions. If refrigerated, a precipitate may form which redissolves with little or no agitation upon reaching room temperature. Product quality is not affected. If the solution remains cloudy, or should insoluble precipitate is noted, the vial should be discarded. Freezing does not adversely affect the product.

An expiry date is given on the outer carton and vial label of the product. It should not be used after this date.