Package leaflet: Information for the patient

CERUBIDIN® 20mg Powder for Concentrate for Solution for Infusion

Daunorubicin hydrochloride

Is this leaflet hard to see or read? Phone 01 403 5600 for help.

Read all of this leaflet carefully before you start taking 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 or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. WHAT CERUBIDIN IS AND WHAT IT IS USED FOR

The name of your medicine is Cerubidin 20mg Powder for Concentrate for Solution for Infusion (called Cerubidin in this leaflet). It belongs to a group of medicines used to treat acute leukaemia. Cerubidin is an immunosuppressant drug that works by attacking and destroying the abnormal white blood cells which are present in a person with leukaemia. Sometimes immunosuppressant drugs can make you susceptible to serious infections.

Daunorubicin in combination with other medicinal products can be used in children with acute lymphocytic blood cancer (acute lymphocytic leukemia) and acute myeloid blood cancer (acute myeloid leukemia).

Information about Leukaemia

Leukaemia is the name for a number of diseases of the white blood cells, which form part of your blood. These cells are produced in your bone marrow. In leukaemia, the white blood cells multiply in an uncontrolled and abnormal way.

The most common signs of leukaemia are:

- Increased number of white cells in the blood. This causes easy bruising and nose bleeds
- Feeling tired, faint, dizzy, having pale skin. These could be symptoms of anaemia
- Extreme tiredness (exhaustion), and headaches
- Bone and joint pain
- Severe infection and fever

2. WHAT YOU NEED TO KNOW BEFORE YOU HAVE CERUBIDIN

Before treatment, you should discuss the risks and benefits of this medicine with your doctor.

Do not have Cerubidin if:

- You are sensitive to or allergic to Cerubidin and other anthracyclines or any of the other ingredients of Cerubidin (listed in Section 6 below) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have inhibition of blood formation in the bone marrow (bone marrow depression).
- You have previously been treated with other anticancer drugs (anthracyclines) such as doxorubicin or epirubicin.
- You have an infection, fever or high temperature. Your doctor will examine you to make sure you do not have any infection before you start treatment with Cerubidin.
- You have heart disease, cardiac failure (insufficient pumping force of the heart; congestive heart failure).
- You have chicken pox or shingles, or you have been in recent contact with anyone who has chicken pox or shingles.
- You are pregnant or breast-feeding.
- You have a lot of mouth ulcers.

Do not have Cerubidin if any of the above applies to you. If you are not sure, talk to your doctor, nurse or pharmacist.

Warnings and Precautions
Talk to your doctor or nurse before you have Cerubidin if:
- You have had radiation treatment to the chest.
- You have any kind of cardiac problem, if you are over 70 or below 15 years of age talk to your doctor. Careful check of your heart may be needed before starting and during treatment. Treatment must be discontinued if any significant problem is detected.
- You have any fluid effusion (extravasation) associated with a burning sensation, followed by a slow death of the skin, which flare up in painful deep ulcers.
- You have had any other medicines to treat leukaemia (or cancer).
- You have or have ever had gout.
- You have or have ever had kidney stones or any other kidney problems.
- You have any liver problems.
- You are to be given a vaccine. Administering live or live attenuated vaccines to patients whose immune system is affected by chemotherapy agents, including daunorubicin, may lead to severe or fatal infections. Patients who receive daunorubicin should not be vaccinated with live vaccines. such as yellow fever vaccine. Dead or inactivated vaccines may be administered. However, such vaccines may be less effective.

Before each treatment with daunorubicin, your doctor will do blood tests to check that you have enough white blood cells (which are important for fighting infection) to receive daunorubicin. In case you experience fever, please contact your doctor immediately.

If you are not sure if any of the above apply to you, talk to your doctor, nurse or pharmacist before being given Cerubidin.

During treatment with Cerubidin
- Hyperuricaemia (high uric acid levels) can occur with Cerubidin treatment. This can occur as a result of a metabolic disorder (Tumor lysis syndrome), symptoms of which can also include fever, chills and feeling extremely tired.
- Your urine, sweat or tear may be coloured in red due to daunorubicin composition. This will last a few days and then return to normal.

- There have also been reports of gastrointestinal disorders such as colitis (inflammation of the colon) and enterocolitis (inflammation of the digestive tract). Treatment should be stopped should these symptoms occur.
- A neurological disorder called Posterior Reversible Encephalopathy Syndrome (PRES) has been reported when treatment with daunorubicin has been used in combination with other cancer treatments. PRES can cause symptoms such as headache, seizures, lethargy, confusion and disturbed vision. If you experience any of these symptoms, you should contact your doctor.

Other medicines and Cerubidin
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor or nurse if you are taking the following:
- Other medicines that may affect the bone marrow or may alter the formation of blood cells, for example:
  - other cancer treatments
  - sulphonamide
  - chloramphenicol (used to treat infection)
  - diphenylhydantoin (used to treat epilepsy)
  - amidopyrine-derivative (used to relieve pain)
  - antiretroviral agents (used to treat HIV infection)
- Cerubidin may decrease the absorption of phenytoin (an epilepsy medicine) from the gastrointestinal tract and therefore also reduce its effectiveness (risk of seizures). If given simultaneously, your doctor should adjust the dose of phenytoin.
- Yellow fever vaccine with daunorubicin hydrochloride is not recommended due to the risk of fatal systemic vaccine disease (see section warnings and precautions)

Pregnancy, breast-feeding and fertility
Do not have Cerubidin if:
- You are pregnant, might become pregnant or think you might be pregnant
- You are breast-feeding or planning to breast-feed

Cerubidin is teratogenic which means it may cause birth defects if used during pregnancy and/or breast-feeding.
Cerubidin should not be used during pregnancy unless clearly necessary.

Women of childbearing potential should use effective contraception measures while being treated with daunorubicin and for 7 months following completion of treatment. Daunorubicin may cause harm to unborn babies when used by pregnant women. If you are pregnant or you become pregnant during treatment with daunorubicin, **get medical advice immediately.**

Men should use effective contraceptive measures and not father a child while being treated with daunorubicin and for four months following completion of treatment.

If you are breast-feeding, you must stop breast-feeding before starting the treatment and must not breast-feed during your treatment.

Ask your doctor, nurse or pharmacist for advice before taking any medicine, if you are pregnant or breastfeeding.

Driving and using machines

Cerubidin causes episodes of nausea and vomiting, confusion, seizures and visual disturbances, which in some cases may lead to an impairment of the ability to drive or use machines.

3. HOW YOU WILL BE GIVEN CERUBIDIN

How Cerubidin is given

- Cerubidin is a medicine used in hospitals
- It will be given to you by a doctor or nurse as an infusion into one of your veins
- It will be given over about 20 minutes (this is called an intravenous infusion)
- It should never be given as a single infusion under the skin or into a muscle
- The site of infusion should not be covered or bandaged

Tell your doctor or nurse straight away if:

- You have any pain, swelling or warmth around the vein where Cerubidin is being infused
- You notice that your face is red while the infusion is being given to you. This may be a sign that the infusion is being given too quickly

How much Cerubidin will be given

- The exact dose will be determined by your doctor. It will depend on your age, height, weight and your general medical condition. The usual dose for a person weighing 70kg (12 stone) would be about 80mg.
- Your course of treatment may be altered, depending on how your body reacts to the medicine.
- Cerubidin may be given alone or in combination with other medicines to treat or prevent side effects.

Tests while having Cerubidin

Your condition will be closely monitored during treatment. This may involve regular blood, urine tests or heart monitoring (called ECG).

If you have any questions about your course of treatment 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 you are worried about side effects you should discuss them with your doctor, who will explain the risks and benefits of your treatment. Some of the side effects can be lessened or treated by other medicines or therapy.

The following side effects may occur:

Very common (may affect more than 1 in 10 people):
Daunorubicin may reduce the number of white blood cells, which fight infection, the red blood cells (leading to fatigue and weakness) and also the blood cells which help the blood to clot (platelets) leading to bleeding disorders such as nosebleeds and bruising.

These effects are more pronounced 2 weeks after having started treatment and usually recover 3 weeks after treatment initiation. However, sometimes, it may take a longer time to recover.

Therefore you must tell your doctor immediately if you experience:

- fever, chills, sore throat, cough or any other symptoms of infection
- bleeding or bruising without injury

Common (may affect up to 1 in 10 people):
- Daunorubicin may also cause heart problems and damage to the heart muscle which can be associated with chest pain and difficulties to breath during efforts and in horizontal position (acute inflammation of the heart). Tell your doctor immediately if you have chest pain, leg pain or feel short of breath. Heart problems may occur even months to years after treatment has ended.
- Inflammation of the digestive tract including mouth (mucositis), diarrhoea, pain in abdomen (belly), vomiting or nausea
- Hair loss (usually reversible)
- Fever

Uncommon (may affect up to 1 in 100 people)
- Skin rash with severe itching and formation of lumps (hives or urticaria)
- Redness of the skin, pain and swelling around the infusion site, caused by leakage from a vein in surrounding tissue
- Inflammation in the digestive tract (enterocolitis), inflammation of the lining of the mouth (stomatitis)

Not known (*frequency cannot be estimated from the available data*):
- Brain swelling with usually temporary symptoms such as headache, vision problems, confusion, seizures
- A neurologic disorder called Posterior Reversible Encephalopathy Syndrome (PRES, also known as Reversible Posterior Leukoencephalopathy Syndrome, RPLS) with symptoms such as abnormal behaviour, headache, abnormal vision, seizures (fits), or confusion, including fatal cases.
- Leukaemia (a type of blood cancer) and other cancers may occur in patients who are treated with daunorubicin together with certain other anticancer treatments.
- Serious allergic reactions which may be life threatening. Signs include flushing, itching, wheezing, and swelling of the mouth, tongue or throat that can interfere with breathing. You should then tell a doctor immediately.
- Generalized oedema due to kidney problems (nephrotic syndrome)
- Fever associated with low white blood cells
- Shock (condition with as characteristics strong decrease in blood pressure, pallor, unrest, weak rapid pulse, clammy and mottled skin and decreased consciousness)
- Bleedings
- Kidney problems due to massive death of tumor cells
- Appearance of abnormal cells in your blood in the long-term
- Slow, fast, or irregular heartbeat
- Hot flashes
- Inflammation of the vein with the formation of a blood clot, often feels like a painful somewhat hard cord with red skin above (thrombophlebitis)
- Lung damage
- Oxygen deficiency in tissue
- Dehydration
- Urinary flow obstruction by precipitation of uric acid crystals (uric acid nephropathy).
- Too high uric acid (hyperuricaemia) in the blood
- Tissue reaction that develops throughout a previously irradiated area (recall phenomenon)
- Discolouration of the skin and nails

- Transient red coloration of urine
- Reduced amount of sperm (oligospermia)
- Lack of sperm (azoospermia)
- Loss of menstrual periods (amenorrhoea)
- Infertility (sterility)
- Pain, chills

Tell your doctor, nurse or pharmacist if any of the side effects gets serious, lasts longer than a few days, or if you notice any side effects not listed in the leaflet.

After stopping treatment
After you have finished your course of treatment, you may still get side effects. Tell your doctor, nurse or pharmacist straightaway if:
- You have difficulty in breathing
- You have swelling of the feet or legs
- You get an uneven or fast heart beat

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 via
HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CERUBIDIN

Your doctor or nurse will keep this medicine in a safe place out of the reach and sight of children.
Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.
The vials should not be stored above 25°C. Store in the original container. Reconstituted solutions of Cerubidin should be stored for up to 24 hours at 2-8°C and protected from light. Cerubidin solution diluted in infusion medium, should be used immediately.

Do not throw away any medicines via waste water. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cerubidin contains
The active substance is daunorubicin hydrochloride. Each vial contains 20mg of daunorubicin as daunorubicin hydrochloride. The other ingredient is mannitol.

What Cerubidin looks like and contents of the pack
Cerubidin 20mg Powder for Concentrate for Solution for Infusion comes as a vial containing a red powder. The solution prepared with this powder is also red.
The vials are available in packs of 1 and 10 vials.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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The following information is intended for healthcare professionals only:

Practical information on preparation and administration of Cerubidin 20mg Powder for Concentrate for Solution for Infusion *(See also Section 3).*

Please refer to full Summary of Product Characteristics before prescribing

Do not store above 25°C. Store in the original container. If prepared aseptically, the reconstituted solution should be stored at 2-8°C protected from light and used within 24 hours. Cerubidin diluted in infusion medium, should be used immediately.

Presentation
Cerubidin is a microcrystalline orange – red hygroscopic sterile powder supplied in vials containing the equivalent of 20mg daunorubicin (as hydrochloride) and mannitol as a stabilizing agent.

Posology and method of administration
Posology

The effect of Cerubidin/Daunorubicin on the disease process and on normal blood precursors cannot be exactly predicted for any particular case. The difference between the incomplete treatment, a satisfactory remission and overdosage with possible irreversible aplasia of the bone marrow depends on the correct choice of dosage, time intervals and total number of doses.

Daunorubicin should be administered with caution when the neutrophil count is <1,500/mm3. Daunorubicin dose reduction should be considered in case of severe neutropenia.

The number of infusions required varies widely from patient to patient and must be determined in each case according to response and tolerance.

Adults:

40 - 60mg/m^2 on alternate days for a course of up to three infusions.

Acute Myelogenous Leukaemia:

45mg/m^2/day is the recommended dose.

Acute Lymphocytic Leukaemia:

45mg/m^2/day is the recommended dose.

Special populations

Pediatric population:

Cerubidin dose for children (over 2 years) is usually calculated based on the body surface area and adjusted to meet individual requirements of each patient, on the basis of clinical response and the patient's haematological status. Courses may be repeated after 3 to 6 weeks.

Current specialized protocols and guidelines should be consulted for appropriate treatment regimen.

For children over 2 years the maximum cumulative dose is 300 mg/m^2

For children under 2 years of age (or below 0.5 m^2 body surface area), the maximum cumulative dose is 10 mg/kg

Elderly

Use with care in patients with inadequate bone marrow reserves. A dosage reduction of up to 50% is recommended.

Renal and hepatic impairment:

The dosage should be reduced in patients with impaired hepatic or renal function (see section 4.4). A 25% reduction is recommended in patients with serum bilirubin concentrations of 1.2-3mg/100ml and a 50% reduction in cases with serum bilirubin or creatinine concentrations above 3 mg/100ml.

Method of administration

For intravenous administration only.

The solution is given *via* the tubing of a freely running intravenous infusion, over a 20 minute period. This technique minimises the risk of thrombosis or perivenous extravasation which can lead to severe cellulitis and vesication.

Cerubidin/Daunorubicin is extremely irritating to tissues and may only be administered intravenously after dilution. Cerubidin/Daunorubicin should be administrated through a large vein and the infusion should be kept free flowing. When second or subsequent infusions are given, the doses and time intervals on the effect on the previous doses and must be the subject of careful deliberation, examination of the peripheral blood and, under some circumstances, of the bone marrow.

Special warnings and special precautions for use

Special warnings

Daunorubicin should only be administered under the direction of a specialist having the facilities for regular monitoring of clinical, biochemical and haematological effects during and after administration.

Urine, sweat or tear may be coloured in red due to daunorubicin composition. This will last a few days and then return to normal.

Daunorubicin has been shown to be carcinogenic in animals. The possibility of a similar effect should be borne in mind when designing the long-term management of the patient.

Precautions for use

Caution is indicated when daunorubicin hydrochloride is used concomitantly with phenytoin due to drug-drug interaction potentially affecting both daunorubicin hydrochloride and phenytoin plasma exposure which can lead to seizure (see section 4.5).

Haematopoietic system

Daunorubicin produces bone marrow depression. Daunorubicin should be administered with caution when the neutrophil count is < 1,500/mm3. Febrile neutropenia has been reported when daunorubicin is given in combination with other antineoplastic treatments.
Monitoring of blood counts prior to and during daunorubicin treatment is recommended, and hematological abnormalities should be treated promptly (see sections 4.2 and 4.8).

Secondary malignancies:

Secondary malignancies (including leukaemia) have been reported when daunorubicin was given in combination with other antineoplastic treatments known to be associated with secondary malignancies (see section 4.8). Secondary malignancies may occur during daunorubicin-containing therapy, or several months or years after the end of therapy. Patients should be monitored for secondary malignancies.

Cardiotoxicity

Extreme caution should be exercised when using the product in patients with cardiac disorders or in the elderly. Cardiotoxicity if it occurs is likely to be heralded by either a persistent tachycardia, shortness of breath, swelling of feet and lower limbs or by minor changes in the electrocardiogram and for this reason an electrocardiographic examination should be made at regular intervals during the treatment.

Cardiotoxicity usually appears within 1 to 6 months after initiation of the therapy. It may develop suddenly and not be detected by routine ECG. It may be irreversible and fatal but responds to treatment if detected early.

The risk may be decreased through regular monitoring of left ventricular ejection fraction

(LVEF) during the course of treatment. Initiation of cardio-protective drugs might be considered to limit the risk of cardiomyopathy, while treatment should be discontinued upon the first sign of cardiomyopathy. A baseline cardiac evaluation with an ECG and either a MUGA scan or an ECHO is recommended, especially in patient with risk factors for increased cardiotoxicity. The appropriate quantitative method for repeated assessment of cardiac function (evaluation of LVEF) includes multi-gated radionuclide angiography (MUGA) or echocardiography (ECHO). ECG changes may be indicative of anthracycline-induced cardiomyopathy, but ECG is not a sensitive or specific method for following anthracycline-related cardiotoxicity.

The risk of congestive heart failure increases significantly when the total cumulative dosage exceeds 600 mg/m^2 body surface area in adults, 300 mg/m^2 in children over 2 years or 10mg/kg bodyweight in children under 2 years. Cardiotoxicity may be more frequent in children and the elderly. The dosage should be modified if previous or concomitant cardiotoxic drug therapy is used.

Hepatic and renal function

Daunorubicin hydrochloride is mainly metabolised in the liver and eliminated via the bile. Hepatic function should be monitored before starting treatment with daunorubicin hydrochloride in order to

prevent complications. The dose should be reduced in case of impaired hepatic function since the toxic effects of the drug may be exacerbated in this population. This should be based on serum bilirubin levels.

An impaired renal function can also lead to increased toxicity. Renal function should therefore be monitored before initiating treatment.

Daunorubicin should be used with care in patients at risk of hyperuricaemia (e.g. in the presence of gout, urate and renal calculi), tumor cell infiltration of the bone marrow and in patients with inadequate bone marrow reserves due to previous cytotoxic drug or radiation therapy. The cumulative dose of daunorubicin should be limited to 400mg/m^2 when radiation therapy to the mediastinum has been previously administered. The dose of daunorubicin should not be repeated in the presence of bone marrow depression or buccal ulceration.

Rapid destruction of a large number of leukaemia cells may cause a rise in the blood uric acid or urea and so it is a wise precaution to check these concentrations three or four times a week during the first week of treatment. Fluids should be administered and allopurinol used in severe cases to prevent the development of hyperuricaemia.

Daunorubicin treatment may lead to hyperuricaemia as a consequence of tumour lysis syndrome.

Infections

Infections should be treated before the start of daunorubicin therapy. If during daunorubicin treatment a patient becomes febrile (regardless of the neutrophil count), treatment with broad spectrum antibiotics should be initiated.

Gastrointestinal disorders

Cases of colitis, entercolitis and neutropenic entercolitis (typhlitis) have been reported in patients treatment with daunorubicin. Treatment discontinuation and prompt appropriate medical management are recommended.

Immunosuppressive effects/Increased sensitivity to infections

The administration of live or live attenuated vaccines to patients whose immune system has been compromised by chemotherapeutic drugs, including daunorubicin, can lead to severe or fatal infections. Patients who receive daunorubicin should not be vaccinated with live vaccines such as yellow fever vaccine. Dead or inactivated vaccines may be administered. Such vaccines may, however, be less effective.

Nervous system disorders

Posterior reversible encephalopathy syndrome (PRES) also known as Reversible Posterior Leukoencephalopathy Syndrome (RPLS):

Cases of PRES have been reported with daunorubicin used in combination chemotherapy. PRES is a neurological disorder which can present with headache, seizure, lethargy, confusion, blindness and other visual and neurologic disturbances. Mild to severe hypertension may be present. Magnetic resonance imaging is necessary to confirm the diagnosis of PRES. In patients with PRES, the discontinuation of daunorubicin treatment should be considered (See section 4.8).

General disorders and administration site condition / Extravasation

Care should be taken to avoid extravasation during intravenous administration. Using catheters or implanted ports reduces the risk of extravasation. All steps should be taking to avoid tissuing and bandages should not be used. Facial flushing or erythematous streaking along the vein indicates too rapid infusion. If tissue necrosis is suspected, the infusion should be stopped immediately and resumed in another vein. Where extravasation has occurred, an attempt should be made to aspirate the fluid back through the needle. The affected area may be injected with hydrocortisone. Sodium bicarbonate (5 ml of 8.4%) may also be injected in the hope that through pH changes the drug will hydrolyse. The opinion of a plastic surgeon should be sought as skin grafting may be required.

Application of ice packs may help decrease local discomfort and also prevent extension. Liberal application of corticosteroid cream and dressing the area with sterile gauze should then be carried out.

Each patient should be given a clinical and bacteriological examination to determine whether infection is present; any infection should be adequately eliminated before treatment with Daunorubicin which might depress the bone marrow to the point where anti-infective agents would no longer be effective. If facilities are available, patients should be treated in a germ-free environment or, where it is not possible, reverse barrier nursing and aseptic precautions should be employed. Anti-infective therapy should be employed in the presence of suspected or confirmed infection and during a phase of aplasia. It should be continued for some time after the marrow has regenerated. Care should also be used in patients at risk of infection.

Personnel handling this product should wear protective clothing and be trained in good handling techniques.

Fertility

Daunorubicin hydrochloride inhibits fertility. Amenorrhea and azoospermia may occur. The severity of this will depends on the dose. Both men and women should take contraceptive measures during and after treatment (see section 4.6). For male or female patients who intend to have a child after completing treatment, genetic counselling is recommended. Male patients should be informed about the possibility of storing their semen before starting treatment with daunorubicin due to the risk of irreversible infertility.

Overdosage

In the event of overdose, all the adverse reactions may be exacerbated. Blood and bone marrow counts should be performed regularly and cardiological, radiological, and ultrasound investigations carried out to define appropriate symptomatic treatment if necessary.

Special precautions for storage

The shelf expiry date for this product shall not exceed 3 years. Do not store above 25°C. Store in the original container. If prepared aseptically, the reconstituted solution should be stored at 2-8°C protected from light and used within 24 hours. . Cerubidin solution diluted in infusion medium should be used immediately.
The reconstituted product is incompatible with heparin sodium injection and dexamethasone sodium phosphate injection.

Special precautions for disposal and other handling

The contents of the vial should be reconstituted with water for injections Ph.Eur. 4ml to give a solution of concentration 5mg per ml. The calculated dose of Cerubidin should be further diluted with normal saline to give a final concentration of 1mg per ml. Once diluted, use immediately. The

solution should be infused over a 20 minute period into the tubing, or side, of a well placed, rapidly flowing i.v. infusion of normal saline (to minimise extravasation and possible tissue necrosis). Alternatively, the Cerubidin may be added to a mini bag of sodium chloride injection 0.9% w/v and this solution infused into the side arm of a rapidly flowing infusion of normal saline.

Special protection information
Cerubidin should only by handled by staff experienced with cytotoxic drugs. Reconstitution should be carried out in a designated area. Protective clothing (including gloves and eye protection) should be worn. Double gloving is recommended for dealing with major spillage's. Waste should be disposed of carefully in suitable separate containers, clearly labelled as to their contents (it should be noted that the patients body fluids and excreta will contain appreciable amounts of antineoplastic agents and they should be treated a hazardous waste). All staff exposed to Cerubidin should be recorded and monitored.
Pregnant staff should not handle Cerubidin.

Spill or Leak Procedures
Daunorubicin infusion may be neutralised with sodium hypochlorite prior to disposal of unused drug or if a vial is accidentally broken. The neutralised drug can be disposed of in the sink.

CERUBIDIN is a Trademark