Summary of Product Characteristics for

EPIRUBICIN HYDROCHLORIDE FOR INJECTION BP 10mg/50mg/100mg/150mg

1. Name of the medicinal product
Epirubicin Hydrochloride for Injection BP

2. Qualitative and quantitative composition
Each vial contains:
Epirubicin Hydrochloride……10mg/50mg/100mg/150mg

3. Pharmaceutical form
Solution for Injection.
Sterile orange red colored lyophilized mass.

4. Clinical particulars
4.1 Therapeutic indications

Epirubicin Hydrochloride is indicated as a component of adjuvant therapy in patients with evidence of axillary node tumor involvement following resection of primary breast cancer.

4.2 Posology and method of administration

Epirubicin Hydrochloride for Injection is administered to patients by intravenous infusion. Epirubicin Hydrochloride for Injection is given in repeated 3- to 4-week cycles.

Recommended Dose

The recommended dose of Epirubicin Hydrochloride is 100 to 120 mg/m^2 administered as an intravenous bolus

CEF-120:	Cyclophosphamide	75 mg/m^2 oral on Days 1 to 14
	Epirubicin hydrochloride injection	60 mg/m^2 intravenously on Days 1 and 8
	5-Fluorouracil	500 mg/m^2 intravenously on Days 1 and 8
	Repeated every 28 days for 6 cycles	
FEC-100	5-Fluorouracil	500 mg/m^2 intravenously on Day 1
	Epirubicin hydrochloride injection	100 mg/m^2 intravenously on Day 1
	Cyclophosphamide	500 mg/m^2 intravenously on Day 1
	Repeat every 21 days for 6 cycles	

Administer Epirubicin Hydrochloride in repeated 3- to 4-week cycles. The total dose of Epirubicin Hydrochloride may be given on Day 1 of each cycle or divided equally and given on Days 1 and 8 of each cycle.

Dose Modifications

Epirubicin Hydrochloride dosage adjustments for hematologic and non-hematologic toxicities within a cycle of treatment, is based on nadir platelet counts <50,000/mm^3, absolute neutrophil counts (ANC) <250/mm^3, neutropenic fever, or Grades 3/4 nonhematologic toxicity. Reduce EPIRUBICIN HYDROCHLORIDE Day 1 dose in subsequent cycles to 75% of the Day 1 dose given in the current cycle. Delay Day 1 chemotherapy in subsequent courses of treatment until platelet counts are ≥100,000/mm^3, ANC ≥1500/mm^3, and nonhematologic toxicities have recovered to ≤ Grade 1.

Cardiac Toxicity

Discontinue Epirubicin Hydrochloride in patients who develop signs or symptoms of cardiomyopathy.

Bone Marrow Dysfunction

Consider administering a lower starting dose (75–90 mg/m^2) for heavily pre-treated patients, patients with pre-existing bone marrow depression, or in the presence of neoplastic bone marrow infiltration. For patients receiving a divided dose of Epirubicin Hydrochloride (Day 1 and Day 8), the Day 8 dose should be 75% of Day 1 if platelet counts are 75,000–100,000/mm^3 and ANC is 1000 to 1499/mm^3. If Day 8 platelet counts are <75,000/mm^3, ANC <1000/mm^3, or Grades 3/4 nonhematologic toxicity has occurred, omit the Day 8 dose.

Hepatic Impairment

In patients with elevated serum AST or serum total bilirubin concentrations, reduce dosage as follows:

- Bilirubin 1.2 to 3 mg/dL or AST 2 to 4 times upper limit of normal 1/2 of recommended starting dose
- Bilirubin > 3 mg/dL or AST > 4 times upper limit of normal 1/4 of recommended starting dose

Renal Impairment

Consider lower doses in patients with severe renal impairment (serum creatinine > 5 mg/dL)

Preparation and Administration Precautions

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Procedures normally used for proper handling and disposal of anticancer drugs should be considered for use with Epirubicin Hydrochloride for Injection.

Protective Measures

The following protective measures should be taken when handling Epirubicin Hydrochloride for Injection:

• Personnel should be trained in appropriate techniques for reconstitution and handling.

• Pregnant staff should be excluded from working with this drug.

• Personnel handling Epirubicin Hydrochloride for Injection should wear protective clothing: goggles, gowns and disposable gloves and masks.

• 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.

• All items used for reconstitution, administration or cleaning (including gloves)

should be placed in high-risk, waste-disposal bags for high temperature incineration. 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
Reconstitution
Prior to use, Epirubicin Hydrochloride for Injection 10mg, 50mg and 100mg vials must be reconstituted with 5 mL, 25 mL and 50 mL, respectively, of Sterile Water for Injection resulting in a solution concentration of 2 mg/mL. Shake vigorously. It may take up to 4 minutes for epirubicin hydrochloride to completely dissolve. Reconstituted solutions are stable for 24 hours when stored at 2°C to 8°C (36 to 46°F) and protected from light or 25°C (77°F) in normal lighting conditions. Epirubicin Hydrorochloride for Injection can be further diluted with Sterile Water for Injection.

Administration
Epirubicin Hydrochloride for Injection should be administered into the tubing of a freely flowing intravenous infusion (0.9% sodium chloride or 5% glucose solution).
Patients receiving initial therapy at the recommended starting doses of 100 to 120mg/m^2 should generally have epirubicin infused over 15 to 20 minutes. For patients who require lower epirubicin starting doses due to organ dysfunction or who require modification of epirubicin doses during therapy, the epirubicin infusion time may be proportionally decreased, but should not be less than 3 minutes. This technique is intended to minimize the risk of thrombosis or perivenous extravasation, which could lead to severe cellulitis, vesication, or tissue necrosis. A direct push injection is not recommended due to the risk of extravasation, which may occur even in the presence of adequate blood return upon needle aspiration. Venous sclerosis may result from injection into small vessels or repeated injections into the same vein. Epirubicin Hydrochloride for Injection should be used within 24 hours of first penetration of the rubber stopper. Discard any unused solution.

4.3 Contraindications

Epirubicin Hydrochloride is contraindicated in patients with:

- Severe myocardial insufficiency
- Recent myocardial infarction or severe arrhythmias, or previous treatment with maximum cumulative dose of anthracyclines
- Severe persistent drug-induced myelosuppression

- Severe hepatic impairment (defined as Child-Pugh Class C or serum bilirubin level greater than 5 mg/dL)
- Severe hypersensitivity to Epirubicin Hydrochloride, other anthracyclines, or anthracenediones.

4.4 Special warnings and precautions for use

Cardiac Toxicity

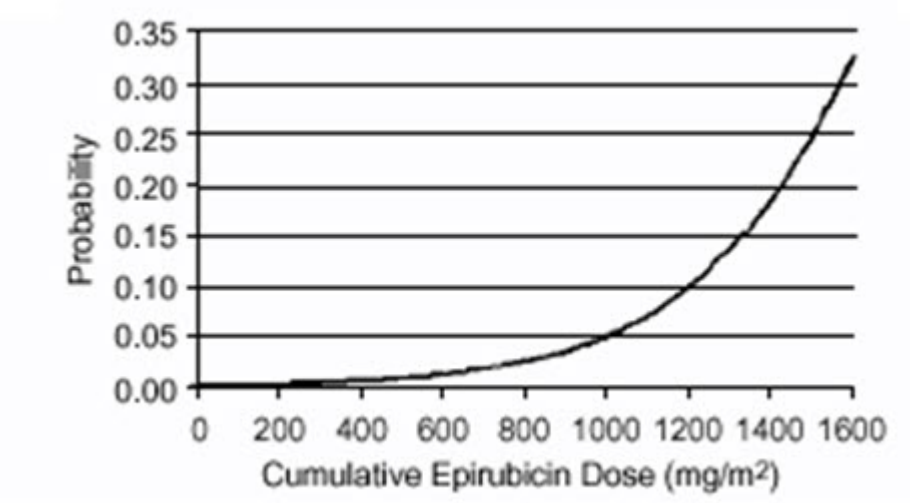
Epirubicin Hydrochloride and other anthracycline drugs can result in either early (or acute) or late (delayed) cardiac toxicity.

The principal manifestations of early cardiac toxicity are sinus tachycardia and/or electrocardiogram (ECG) abnormalities such as non-specific ST-T wave changes. However, tachycardia (including premature ventricular contractions and ventricular tachycardia), bradycardia, as well as atrioventricular and bundle-branch block have been reported. Early cardiac toxicity does not usually predict the subsequent occurrence of delayed cardiotoxicity and generally should not be considered a reason for suspending treatment with Epirubicin Hydrochloride.

Delayed cardiac toxicity is manifested by reduced left ventricular ejection fraction (LVEF) and/or signs and symptoms of congestive heart failure (CHF). If it occurs, late cardiotoxicity usually develops late during therapy with Epirubicin Hydrochloride or within 2 to 3 months after completion of treatment, but there are reports of it occurring several months to years after treatment termination. In a retrospective survey, including 9144 patients, mostly with solid tumors in advanced stages, the probability of developing CHF increased with increasing cumulative doses of Epirubicin Hydrochloride (Figure 1). In another retrospective survey of 469 Epirubicin Hydrochloride -treated patients with metastatic or early breast cancer, the reported risk of CHF was comparable to that observed in the larger study of over 9000 patients.

Given the risk of cardiac toxicity, cumulative doses of 900 mg/m^2 Epirubicin Hydrochloride should generally be avoided.

Figure 1. Risk of CHF in 9144 Patients Treated with EPIRUBICIN HYDROCHLORIDE



Prior history of cardiovascular disease, prior or concomitant radiotherapy to the mediastinal/pericardial area, previous therapy with other anthracyclines or anthracenediones, and concomitant use of other cardiotoxic drugs, increase the risk of developing late cardiac toxicity. Avoid administration of Epirubicin Hydrochloride in combination with other cardiotoxic drugs. Although not formally tested, it is probable that the toxicity of Epirubicin Hydrochloride and other anthracyclines or anthracenediones is additive. Cardiac toxicity with Epirubicin Hydrochloride may occur at lower cumulative doses whether or not cardiac risk factors are present. Patients receiving Epirubicin Hydrochloride after stopping treatment with other cardiotoxic drugs, especially those with long half-lives such as trastuzumab, may be at increased risk of developing cardiotoxicity.

Perform a baseline ECG and evaluation of LVEF prior to initiating treatment with Epirubicin Hydrochloride. Monitor LVEF during the course of treatment and consider discontinuation of Epirubicin Hydrochloride if LVEF decrease and/or signs or symptoms of CHF develop. Closely monitor patients with other risk factors for cardiac toxicity, particularly prior administration of anthracycline or anthracenedione.

Secondary Malignancies

The risk of developing secondary acute myelogenous leukemia and myelodysplastic syndrome (MDS), is increased following treatment with Epirubicin Hydrochloride and other anthracyclines. Cumulative risk of secondary acute myelogenous leukemia or myelodysplastic syndrome (AML/MDS) of about 0.27% at 3 years, 0.46% at 5 years, and 0.55% at 8 years. These leukemias generally occur within 1 to 3 years of treatment.

Extravasation and Tissue Necrosis

Extravasation of Epirubicin Hydrochloride can result in severe local tissue injury manifesting as blistering, ulceration, and necrosis requiring wide excision of the affected area and skin grafting. Extravasation should be considered if a patient experiences a burning or stinging sensation or shows other evidence indicating peri-venous infiltration or extravasation; however, extravasation may be present in patients who do not experience a stinging or burning sensation or when blood return is present on aspiration of the infusion needle.

Venous sclerosis may result from an injection into a small vessel or from repeated injections into the same vein. Administer Epirubicin Hydrochloride slowly into the tubing of a freely running intravenous infusion. Patients receiving initial therapy at the recommended starting doses of 100–120 mg/m^2 should have Epirubicin Hydrochloride infused over 15–20 minutes. For patients who require lower Epirubicin Hydrochloride starting doses due to organ dysfunction or who require modification of Epirubicin Hydrochloride doses during therapy, the Epirubicin Hydrochloride infusion time may be proportionally decreased, but should not be less than 3 minutes. If possible, avoid veins over joints or in extremities with compromised venous or lymphatic drainage. Facial flushing, as well as local erythematous streaking along the vein, may be indicative of excessively rapid administration. It may precede local phlebitis or thrombophlebitis.

Immediately terminate infusion and restart in another vein if a burning or stinging sensation indicates perivenous infiltration. Perivenous infiltration may occur without causing pain. If extravasation is suspected, immediately discontinue the intravenous injection or continuous intravenous infusion. Apply ice to the site intermittently for 15 minutes, 4 times a day for 3 days. If appropriate, administer dexrazoxane at the site of extravasation as soon as possible and within the first 6 hours after extravasation.

Severe Myelosuppression

Epirubicin Hydrochloride can cause severe myelosuppression. Obtain complete blood counts prior to each treatment and carefully monitor patients during treatment for possible clinical complications due to myelosuppression. Delay the next dose of Epirubicin Hydrochloride if severe myelosuppression has not improved. Consider dose reduction for patients with prolonged myelosuppression based on the severity of reaction.

Use in Patients with Hepatic Impairment

The major route of elimination of epirubicin is the hepatobiliary system. Evaluate serum total bilirubin and AST levels before and during treatment with Epirubicin Hydrochloride. Patients with elevated bilirubin or AST may experience slower clearance of drug with an increase in overall toxicity. Lower doses are recommended in these patients. Patients with severe hepatic impairment have not been evaluated; therefore, do not use Epirubicin Hydrochloride in this patient population.

Use in Patients with Renal Impairment

Assess serum creatinine before and during therapy. Dosage adjustment is necessary in patients with serum creatinine >5 mg/dL. Patients undergoing dialysis have not been studied.

Tumor-Lysis Syndrome

Epirubicin Hydrochloride can induce tumor lysis syndrome in patients with rapidly growing tumors. Evaluate blood uric acid levels, potassium, calcium, phosphate, and creatinine after initial treatment. Consider hydration, urine alkalinization, and prophylaxis with allopurinol to minimize hyperuricemia and potential complications of tumor lysis syndrome.

Immunosuppressant Effects/Increased Susceptibility to Infections

Administration of live or live-attenuated vaccines in patients immunocompromised by chemotherapeutic agents including epirubicin, may result in serious or fatal infections. Avoid vaccination with a live vaccine in patients receiving Epirubicin Hydrochloride. Killed or inactivated vaccines may be administered; however, the response to such vaccines may be diminished.

Thrombophlebitis and Thromboembolic Events

Thrombophlebitis and thromboembolic events, including pulmonary embolism (in some cases fatal) have been reported with the use of Epirubicin Hydrochloride.

Potentiation of Radiation Toxicity and Radiation Recall

Epirubicin Hydrochloride can increase radiation-induced toxicity to the myocardium, mucosa, skin, and liver. Radiation recall, including but not limited to cutaneous and pulmonary toxicity, can occur in patients who receive Epirubicin Hydrochloride after prior radiation therapy.

Embryo-Fetal Toxicity

Based on findings from animals and its mechanism of action, Epirubicin Hydrochloride can cause fetal harm when administered to a pregnant woman; avoid the use of Epirubicin Hydrochloride during the

1st trimester. Available human data do not establish the presence or absence of major birth defects and miscarriage related to the use of epirubicin during the 2nd and 3rd trimesters. In animal reproduction studies, epirubicin was embryo-fetal lethal and caused structural abnormalities in rats and rabbits at doses less than the maximum recommended human dose on a body surface area basis. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise female patients of reproductive potential to use effective contraception during treatment and for 6 months after the last dose of Epirubicin Hydrochloride. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of Epirubicin Hydrochloride. Advise male patients with pregnant partners to use condoms during treatment and for at least 7 days after the last dose of Epirubicin Hydrochloride.

4.5 Interaction with other medicinal products and other forms of interaction

Cardiotoxic Agents
Closely monitor cardiac function when Epirubicin Hydrochloride is used in combination with other cardiotoxic agents. Patients receiving Epirubicin Hydrochloride after stopping treatment with other cardiotoxic agents, especially those with long half-lives such as trastuzumab, may be at an increased risk of developing cardiotoxicity. Trastuzumab may persist in the circulation for up to 7 months. Therefore, avoid anthracycline-based therapy for up to 7 months after stopping trastuzumab when possible. Monitor the patient's cardiac function closely if anthracyclines are used before this time.
Concomitant use of Epirubicin Hydrochloride with other cardioactive compounds that could cause heart failure (e.g., calcium channel blockers), requires close monitoring of cardiac function throughout treatment.

Cimetidine
Cimetidine increases the exposure to epirubicin. Discontinue cimetidine during treatment with Epirubicin Hydrochloride.

Other Cytotoxic Drugs
Epirubicin Hydrochloride used in combination with other cytotoxic drugs may show on-treatment additive toxicity, especially hematologic and gastrointestinal effects.
Paclitaxel:
The administration of epirubicin immediately prior to or after paclitaxel increased the systemic exposure of epirubicin, epirubicinol and 7-deoxydoxorubicin aglycone.
Docetaxel:
The administration of epirubicin immediately prior to or after docetaxel did not have an effect on the systemic exposure of epirubicin, but increased the systemic exposure of epirubicinol and 7-deoxydoxorubicin aglycone.

Radiation Therapy
There are few data regarding the coadministration of radiation therapy and Epirubicin Hydrochloride. In adjuvant trials of Epirubicin Hydrochloride -containing CEF-120 or FEC-100 chemotherapies, breast irradiation was delayed until after chemotherapy was completed. This practice resulted in no apparent increase in local breast cancer recurrence relative to published accounts in the literature. A small number of patients received Epirubicin Hydrochloride -based chemotherapy concomitantly with radiation therapy but had chemotherapy interrupted in order to avoid potential overlapping toxicities. It is likely that use of Epirubicin Hydrochloride with radiotherapy may sensitize tissues to the cytotoxic actions of irradiation.

Administration of Epirubicin Hydrochloride after previous radiation therapy may induce an inflammatory recall reaction at the site of the irradiation.

4.6 Fertility, pregnancy and lactation

Fertility

Females - Based on clinical findings and animal studies, Epirubicin Hydrochloride may impair female fertility and result in amenorrhea. Premature menopause can occur. Recovery of menses and ovulation is related to age at treatment.

Males - Based on its mechanism of action and genotoxicity studies, advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of Epirubicin Hydrochloride. Advise male patients with pregnant partners use condoms during treatment and for at least 7 days after the last dose of Epirubicin Hydrochloride.

Pregnancy

Based on findings from animal studies and its mechanism of action, Epirubicin Hydrochloride can cause fetal harm when administered to a pregnant woman; avoid the use of Epirubicin Hydrochloride during the 1st trimester. Available human data do not establish the presence or absence of major birth defects and miscarriage related to the use of epirubicin during the 2nd and 3rd trimesters. There are reports of fetal and/or neonatal cardiotoxicity following in utero exposure to epirubicin. In animal reproduction studies in pregnant rats, epirubicin was embryo-fetal lethal and caused structural abnormalities when administered during organogenesis at doses less than the maximum recommended human dose on a body surface area basis. Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

Lactation

There are no data on the presence of epirubicin in human milk, the effects on the breastfed child, or the effects on milk production. Epirubicin is present in rat milk. When a drug is present in animal milk it is likely the drug will be present in human milk. Because of the potential for serious adverse reactions in the breastfed child, advise lactating women not to breastfeed during treatment with Epirubicin Hydrochloride and for at least 7 days after the last dose.

4.7 Effects on ability to drive and use machines

There have been no reports of particular adverse events relating to effects on ability to drive and to use machines.

4.8 Undesirable effects

The following undesirable effects have been observed and reported during treatment with epirubicin with the following frequencies. The adverse effects are listed below by system organ class and frequency (very common ≥ 1/10; common ≥ 1/100 to < 1/10; uncommon ≥1/1,000 to <1/100; not known (cannot be estimated from available data)).

System Organ Class	Frequency	Adverse Event
Infections and infestations	Very Common	Infection, Conjunctivitis
	Uncommon	Septic shock, Sepsis*, Pneumonia*

Neoplasms benign, malignant and unspecified (including cysts and polyps)	Uncommon	Acute myeloid leukaemia, Acute lymphocytic leukaemia
Blood and lymphatic system disorders	Very Common	Anaemia, Leukopenia, Neutropenia, Thrombocytopenia Febrile neutropenia
Immune system disorders	Rare	Anaphylactic reaction*
Metabolism and nutrition disorders	Common	Decreased appetite Dehydration*
	Rare	Hyperuricaemia*
Eye disorders	Very Common	Keratitis
Cardiac disorders	Common	Ventricular tachycardia, Atrioventricular block, Bundle branch block, Bradycardia, Cardiac failure congestive
Vascular disorders	Very Common	Hot flush, Phlebitis*
	Common	Haemorrhage*, Flushing*
	Uncommon	Embolism, Embolism arterial*, Thrombophlebitis*
	Frequency not known	Shock*
Respiratory, thoracic and mediastinal disorders	Uncommon	Pulmonary embolism*
Gastrointestinal disorders	Very Common	Nausea, Vomiting, Stomatitis, Mucosal inflammation, Diarrhoea
	Common	Gastrointestinal pain*, Gastrointestinal erosion*, Gastrointestinal ulcer*
	Uncommon	Gastrointestinal haemorrhage*
	Frequency not known	Abdominal discomfort, Pigmentation buccal*
Skin and subcutaneous tissue disorders	Very Common	Alopecia, Skin toxicity
	Common	Rash/Pruritus, Nail pigmentation*, Skin disorder, Skin hyperpigmentation*
	Uncommon	Urticaria* Erythema*
	Frequency not known	Photosensitivity reaction*
Renal and urinary disorders	Very Common	Chromaturia*†
Reproductive system and breast disorders	Very Common	Amenorrhoea
General disorders and administration site conditions	Very Common	Malaise, Pyrexia*
	Common	Chills*
	Uncommon	Asthenia

Investigations	Very Common	Transaminases abnormal
	Common	Ejection fraction decreased
Injury, poisoning and procedural complications	Very Common	Chemical cystitis*§
	Frequency not known	Recall phenomenon*Δ

***** ADR identified post-marketing.
† Red coloration of urine for 1 to 2 days after administration.
§ Following intravesical administration.
Δ Hypersensitivity to irradiated skin (radiation-recall reaction).

4.9 Overdose

There is no known antidote for overdoses of Epirubicin Hydrochloride. If an overdose occurs, provide supportive treatment (including antibiotic therapy, blood and platelet transfusions, colony-stimulating factors, and intensive care as needed) until the recovery of toxicities. Delayed CHF has been observed months after anthracycline administration. Observe patients carefully over time for signs of CHF and provided with appropriate supportive therapy.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antineoplastic agent. ATC code: L01D B03

Epirubicin is a cytotoxic active antibiotic from the anthracycline group. The mechanism of action of epirubicin is related to its ability to bind to DNA. Cell culture studies have shown rapid cell penetration, localisation in the nucleus and inhibition of nucleic acid synthesis and mitosis. Epirubicin has proved to be active on a wide spectrum of experimental tumours including L1210 and P388 leukaemias, sarcomas SA180 (solid and ascitic forms), B16 melanoma, mammary carcinoma, Lewis lung carcinoma and colon carcinoma 38. It has also shown activity against human tumours transplanted into athymic nude mice (melanoma, mammary, lung, prostatic and ovarian carcinomas).

5.2 Pharmacokinetic properties

In patients with normal hepatic and renal function, plasma levels after I.V. injection of 60-150mg/m^2 of the drug follow a tri-exponential decreasing pattern with a very fast first phase and a slow terminal phase with a mean half-life of about 40 hours. These doses are within the limits of pharmacokinetic linearity both in terms of plasma clearance values and metabolic pathway. The major metabolites that have been identified are epirubicinol (13-OH-epirubicin) and glucuronides of epirubicin and epirubicinol.
The 4'-O-glucuronidation distinguishes epirubicin from doxorubicin and may account for the faster elimination of epirubicin and its reduced toxicity. Plasma levels of the main metabolite, the 13-OH-derivative (epirubicinol) are consistently lower and virtually parallel those of the unchanged drug.
Pharmorubicin is eliminated mainly through the liver; high plasma clearance values (0.9 l/min) indicate that this slow elimination is due to extensive tissue distribution. Urinary excretion accounts for approximately 9-10% of the administered dose in 48 hours.
Biliary excretion represents the major route of elimination, about 40% of the administered dose being recovered in the bile in 72 hours.
The drug does not cross the blood-brain barrier.

5.3 Preclinical safety data

The main target organs in rat, rabbit and dog following repeated dosing were the haemolymphopoietic system, GI tract, kidney, liver and reproductive organs. Epirubicin was also cardiotoxic in the species tested.
It was genotoxic, and, like other anthracyclines, carcinogenic in rats.
Epirubicin was embryotoxic in rats. No malformations were seen in rats or rabbits, but like other anthracyclines and cytotoxic drugs, epirubicin must be considered potentially teratogenic.
A local tolerance study in rats and mice showed extravasation of epirubicin causes tissue necrosis.

6. Pharmaceutical particulars

6.1 List of excipients

Lactose Monohydrate BP
Methyl Paraben BP
Hydrochloric Acid BP
Sodium Hydroxide BP
Water for Injection BP

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in list of excipients.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store below 30^0C.
Protect from light.

6.5 Nature and contents of container

Epirubicin Hydrochloride for Injection is available in a single use vial containing Epirubicin Hydrochloride BP 10mg/50mg/100mg.

6.6 Special precautions for disposal and other handling

The injection solution contains no preservative and any unused portion of the vial should be discarded immediately. Epirubicin Hydrochloride is compatible with glucose 5% and sodium chloride 0.9%.
Guidelines for the safe handling and disposal of antineoplastic agents:
1. If an infusion solution is to be prepared, this should be performed by trained personnel under aseptic conditions.
2. Preparation of an infusion solution should be performed in a designated aseptic area.

3. Adequate protective disposable gloves, goggles, gown and mask should be worn.
4. Precautions should be taken to avoid the medicinal product accidentally coming into contact with the eyes, irrigate with large amounts of water and/or 0.9% sodium chloride solution. Then seek medical evaluation by a physician.
5. In case of skin contact, thoroughly was the affected area with soap and water or sodium bicarbonate solution. However, do not abrade the skin by using a scrub brush. Always wash hands after removing gloves.
6. Spillage or leakage should be treated with dilute sodium hypochlorite (1% available chlorine) solution, preferably by soaking, and then water. All cleaning materials should be disposed of as detailed below.
7. Pregnant staff should not handle the cytotoxic preparation.
8. Adequate care and precautions should be taken in the disposal of items (syringes, needles etc) used to reconstitute and/or dilute cytotoxic medicinal products. Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorization holder

<< Marketing authorization holder details >>

8. Marketing authorization number(s)

<< Marketing authorization number details >>

9. Date of first authorization/renewal of the authorization

<< Date of authorization/renewal >>

10. Date of revision of the text

17-Nov-2023

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