

**ADLEY**

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

**ADOXI
INJECTION**

Docetaxel Concentrate IP 20mg/0.5ml, 80mg/2ml, 120mg/3ml

ADOXI INJECTION

Each ml contains
DOCETAXEL Trihydrate BP
eq to anhydrous Docetaxel 40mg
Polysorbate 80 IP qs

DESCRIPTION

Docetaxel is an antineoplastic agent belonging to the taxoid family. It is prepared by semisynthesis beginning with a precursor extracted from the renewable needle biomass of yew plants. The Chemical name for docetaxel is (2R, 3S)-N-Carboxy-3-phenylisoserine, N-tert-butylester, 13-ester with 5-(20-epoxy-1, 2 (47) 10(13) hexahydroxytax 11 en-9-one 4-acetate 2-benzoate, trihydrate.

Docetaxel is a white to almost white powder with an empirical formula of $C_{42}H_{54}NO_{14} \cdot 3H_2O$ and a molecular weight of 861.9. It is highly lipophilic and practically insoluble in water.

CLINICAL PHARMACOLOGY:

Docetaxel is an antineoplastic agent that acts by disrupting the microtubular network in cells that is essential for mitotic and interphase cellular functions. Docetaxel binds to free tubulin and promotes the assembly of tubulin into stable microtubules while simultaneously inhibiting their disassembly. This leads to the production of microtubule bundles without normal function and to the stabilization of microtubules, which results in the inhibition of mitosis in cells. Docetaxel's binding to microtubules does not alter the number of protofilaments in the bound microtubules, a feature which differs from most spindle poisons currently in clinical use.

HUMAN PHARMACOKINETICS

The pharmacokinetics of docetaxel has been evaluated in cancer patients after administration of 20-115 mg/m² in phase 1 studies. The area under the curve (AUC) was dose proportional following doses of 70-115 mg/m² with infusion times of one to two hours. Docetaxel's pharmacokinetic profile is consistent with a three-compartment pharmacokinetic model, with half-lives for the α , β and γ phase of 4 min, 36 min, and 11.1 hr, respectively. This initial rapid decline represents distribution to the peripheral compartments and the late (terminal) phase is due, in part, to a relatively slow efflux of docetaxel from the peripheral compartment.

Mean values for total body clearance and steady state volume of distribution were 21 L/h/m² and 113 L, respectively. Mean total body clearance for Japanese patients dosed at the range of 10-90 mg/m² was similar to that of European / American populations dosed at 100 mg/m², suggesting no significant difference in the elimination of docetaxel in the two populations.

A study of ¹⁴C - docetaxel was conducted in three cancer patients. Docetaxel was eliminated in both the urine and faeces following oxidative metabolism of the tert - butyl ester group, but fecal excretion was the main elimination route. Within seven days, urinary and fecal excretion accounted for approximately 6% and 75% of the administered radioactivity, respectively. About 80% of the radioactivity recovered in faeces is excreted during the first 48 hours as one major and 3 minor metabolites with very small amounts (less than 8%) of unchanged drug. Based on in Vitro studies, isoenzymes of the cytochrome P4503A (CYP3A) Subfamily appear to be involved in docetaxel metabolism.

A population pharmacokinetic analysis was carried out after docetaxel treatment of 535 patients dosed at 100 mg/m². Pharmacokinetic parameters estimated by this analysis were very close to those estimated from phase 1 studies. The pharmacokinetics of docetaxel were not influenced by age or gender and docetaxel total body clearance was not modified by pretreatment with dexamethasone. In patients with clinical chemistry data suggestive of mild to moderate liver function impairment (SGOT and / or SGPT) 1.5 times the upper limit of normal (ULN) concomitant with alkaline phosphatase > 2.5 times ULN, total body clearance was lowered by an average of 27% resulting in a 38% increase in systemic exposure (AUC).

This average, however, includes a substantial range and there is, at present, no measurement that would allow recommendation for dose adjustment in such patients. Patients with combined abnormalities of transaminase and alkaline phosphatase should, in general not be treated with ADOXI.

In Vitro studies showed that docetaxel is about 94% protein bound, mainly to a β 2-glycoprotein, albumin, and lipoproteins. In three cancer patients, in vitro binding to plasma proteins was found to be approximately 97%. Dexamethasone dose not affect the protein binding of docetaxel.

INDICATIONS 124 ADOXI is indicated for the treatment of patients with locally advanced or metastatic breast cancer, who have progressed during anthracycline -based therapy or have relapsed during anthracycline-based adjuvant therapy. It is also indicated for the treatment of advanced or metastatic non-small cell lung cancer after failure of platinum containing chemotherapy.

CONTRAINDICATIONS: ADOXI is contraindicated in patients who have a history of severe hypersensitivity reactions to docetaxel or to other drugs formulated with polysorbate 80 IP. ADOXI should not be used in patients with neutrophil counts < 1,500 cells/mm³.

WARNINGS:

Adoxi Injection should be administered under the supervision of a qualified physician experienced in the use of antineoplastic agents. Appropriate management of complications is possible only when adequate diagnostic and treatment facilities are readily available.

Toxic Deaths : Docetaxel administered at 100 mg/m² was associated with deaths considered possibly or probably related to treatment in 2.4% (34/1435) of patients with normal liver function and in 11% (6/55) of patients with abnormal liver function and in 11% (6/55) of patients with abnormal liver function (SGOT and / or SGPT > 1.5 times ULN together with AP > 2.5 times ULN). Among patients dosed at 60 mg/m², mortality related to treatment occurred in 0.6% (3/481) of patients with normal liver function and in 3 to 74 patients with abnormal liver function. Approximately half of these deaths occurred during the first cycle. Sepsis accounted for the majority of the deaths.

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ADOXI

Premedication Regimen: Although the optimal premedication regimen is not defined, all patients should be premedicated with oral corticosteroids such as dexamethasone 16 mg per day (e.g., 8 mg BID) for 5 days starting 1 day prior to KD-Taxel to reduce the severity of fluid retention and hypersensitivity reactions.

Hypersensitivity Reactions: Patients should be observed closely for hypersensitivity reactions, especially during the first and second infusions. Severe hypersensitivity reactions characterized by hypotension and/or bronchospasm, or generalized rash/erythema occurred in 0.9% of patients who received the recommended premedication. Hypersensitivity reactions requiring discontinuation of the docetaxel infusion were reported in 5 out of 1260 patients who did not receive premedication. Patients with a history of severe hypersensitivity reactions should not be rechallenged with ADOXI.

Hematologic Effects: Neutropenia (less than 2000 neutrophils/mm²) occur in nearly all patients given 100 mg/m², and 75-80% of patients given 60-75 mg/m². Frequent monitoring of blood counts is, therefore, essential so that dose can be adjusted. ADOXI should not be administered to patients with neutrophils < 1,500 cells/mm².

Three breast cancer patients with severe liver impairment (bilirubin > 1.7 times ULN) developed fatal gastrointestinal bleeding associated with severe drug-induced thrombocytopenia.

Hepatic Impairment: ADOXI should generally not be given to patients with bilirubin > upper limit of normal (ULN), or to patients with SGOT and/or SGPT > 15x ULN concomitant with alkaline phosphatase > 2.5 x ULN. Patients with elevations of bilirubin or abnormalities of transaminase concurrent with alkaline phosphatase are at increased risk for the development of grade 4 neutropenia, febrile neutropenia, infections, severe thrombocytopenia, severe stomatitis, severe skin toxicity, and toxic death.

Patient with isolated elevations of transaminase > 1.5 x ULN also had a higher rate of febrile neutropenia grade 4 but did not have an increased incidence of toxic death. Bilirubin, SGOT or SGPT, and alkaline phosphatase values should be obtained prior to each cycle of ADOXI therapy and reviewed by the treating physician.

FLUID RETENTION: Severe fluid retention occurred in 6% of patients despite use of a 5-day dexamethasone premedication regimen. It was characterized by one or more of the following events: poorly tolerated peripheral edema, generalized edema, pleural effusion requiring urgent drainage, dyspnea at rest, cardiac tamponade, or pronounced abdominal distention (due to ascites).

Pregnancy: Docetaxel can cause fetal harm when administered to pregnant women. Studies in both rats and rabbits at doses equal to or greater than 0.3 and 0.03 mg/kg/day, respectively (about 1/50 and 1/300 the daily maximum recommended human dose on a mg/m² basis), administered during the period of organogenesis, have shown that docetaxel is embryotoxic and fetotoxic (characterized by intrauterine mortality, increased resorption, reduced fetal weight, and fetal ossification delay). The doses indicated above also caused maternal toxicity. There are no adequate and well-controlled studies in pregnant women using docetaxel.

If ADOXI is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus or potential risk for loss of the pregnancy. Women of childbearing potential should be advised to avoid becoming pregnant during therapy with ADOXI.

PRECAUTIONS:

General: Responding patients may not experience an improvement in performance status on therapy and may experience worsening. The relationship between changes in performance status, response to therapy and treatment-related side effects has been established.

Hematologic Effects: In order to monitor the occurrence of myelotoxicity, it is recommended that frequent peripheral blood cell counts be performed on all patients receiving ADOXI. Patients should not be retreated with subsequent cycles of ADOXI, until neutrophils recover to a level > 1,500 cells/mm² and platelets recover to a level > 100,000 cells/mm².

A 25% reduction in the dose of docetaxel is recommended during subsequent cycle following severe neutropenia (<500 cells/mm²) lasting 7 days or more, febrile neutropenia, or grade 4 infections in a docetaxel cycle.

Hypersensitivity Reactions: Hypersensitivity reactions may occur within a few minutes following initiation of a ADOXI infusion. If minor reactions such as flushing or localized skin reactions occur, of ADOXI and aggressive therapy. All patients should be premedicated with an oral corticosteroid prior to the initiation of the infusion of ADOXI.

Cutaneous: Localized erythema of the extremities with edema followed by desquamation has been observed. In case of severe skin toxicity, an adjustment in dosage is recommended (see Dosage and Administration section). **Fluid Retention:** Severe fluid retention has been reported following docetaxel therapy. Patients should be premedicated with oral corticosteroids prior to each administration to reduce the incidence and severity of fluid retention (see DOSAGE AND ADMINISTRATION section). Patients with pre-existing effusions should be closely monitored from the first dose for the possible exacerbation of the effusions. In patients who received the recommended premedication, moderate fluid retention was completely, but sometimes slowly reversible following discontinuation of docetaxel (median of 29 weeks). The median cumulative dose to onset of moderate or severe fluid retention was 705 mg/m² in patients receiving premedication. Patients developing peripheral edema may be treated with standard measure, e.g., salt restriction, oral diuretic (S).

Neurologic: Severe neurosensory symptoms (paresthesia, dysesthesia, pain) were observed among 7% of 134 patients with anthracycline-resistant breast cancer. When these occur, dosage must be adjusted, if symptoms persist, treatment should be discontinued (see DOSAGE ADMINISTRATION section). Patients who experienced neurotoxicity in clinical trials and for whom follow-up information on the complete resolution of the event was available has spontaneous reversal of symptoms within a median of 5 weeks from onset (range: 0 to 106 weeks) and only about 3.8% of patients required discontinuation due to neurotoxicity. Peripheral motor neuropathy mainly manifested as distal extremity weakness occurred in 13.4% (7.1% severe) of the 127 anthracycline-resistant breast cancer patients with normal LFTs. No neuromotor toxicity was reported in the 7 patients with elevated LFTs.

Asthenia: Severe asthenia has been reported in 111% of the patients but has led to treatment discontinuation in only 2.6% of the patients. Severe asthenia was reported in 23% of 134 patients with anthracycline-resistant breast cancer and 5.5% of the 786 cycles received. Symptoms of fatigue and weakness may last a few days up to several weeks and may be associated with deterioration of performance status in patients with progressive disease.

Drug Interactions: There have been no formal clinical studies to evaluate the drug interactions of docetaxel with other medications. In Vitro studies have shown that the metabolism of docetaxel may be modified by the concomitant administration of compounds that induce, inhibit or are metabolized by cytochrome P450 3A4, such as cyclosporine, terfenadine, ketoconazole, erythromycin, and troleandomycin. Caution should be exercised with these drugs when treating patients receiving as there is a potential for a significant interaction.

CARCINOGENICITY, MUTAGENICITY, IMPAIRMENT OF FERTILITY: No studies have been conducted to assess the carcinogenic potential of docetaxel. Docetaxel has been shown to be clastogenic in the in vitro chromosome aberration test in CHO-K1 cells and in the in vivo micronucleus test in the mouse, but it did not induce mutagenicity in the Ames test, or the CHO/HGPRT gene mutation assays. Docetaxel produced no impairment of fertility in rats when administered in multiple I.V. doses of up to 3 mg/kg (about 1/50 the t were

recommended human dose on a mg/m^2 basis), but decreased testicular weight were reported. This correlates with findings of a 10-cycle toxicity study (during once every 21 days for 6 months) in rats and dogs in which testicular atrophy or degeneration was observed at I.V. doses of 5 mg/kg in rats and 0.375 mg/kg in dogs (about 1/3 and 1/15 the recommended human dose on a mg/m^2 basis, respectively). An increased frequency of dosing in rats produced similar effects at lower dose levels.

Pregnancy: Docetaxel can cause fetal harm when administered to pregnant women. Studies in both rats and rabbits at doses equal to or greater than 0.3 and 0.03 $\text{mg}/\text{kg}/\text{day}$, respectively (about 1/50 and 1/300 the daily maximum recommended human dose on a mg/m^2 basis), administered during the period of organogenesis, have shown that it is embryotoxic and fetotoxic (Characterized by intrauterine mortality, increased resorption, reduced fetal weight, and fetal ossification delay). The doses indicated above also caused maternal toxicity.

Nursing Mothers: It is not known whether ADOXI is excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from ADOXI mothers should discontinue nursing prior to taking the drug.

Pediatric use: The safety and effectiveness of ADOXI in Paediatric patients have been established.

ADVERSE REACTIONS:

There were 1495 patients enrolled in 37 clinical trials conducted in North American and Europe (624 breast carcinoma patients and 866 patients with other tumor types) who received docetaxel at an initial dose of 100 mg/m^2 every 3 weeks. Five patients were not evaluable for toxicity since they discontinued docetaxel treatment due to acute hypersensitivity reactions with the first infusion. At least 95% of these patients did not receive hematopoietic support.

Hematologic: Bone marrow suppression is the major dose-limiting toxicity of docetaxel. Neutropenia is reversible and not cumulative. The median day to nadir was 8 days, while the median duration of severe neutropenia (<500 cells/ mm^3) was 7 days. Among patients with normal liver function treated with docetaxel, severe neutropenia occurred in 76% and lasted for more than 7 days in 4.3% of cycles. Anemia was reported in 89.5% with severe cases being reported in 8.4% of the patients).

Febrile neutropenia (<500 cells/ mm^3 with IV antibiotics and / or hospitalization) occurred in 11.8% of the patients with normal liver function (3% of the cycles). Infections episodes occurred in 21.7% of the patients (6.2% of the cycles) and were fatal in 1.6% of those treated with docetaxel (1.4% in breast cancer patients).

Thrombocytopenia ($<100,000$ cells/ mm^3) occurred in 7.5% of the patients with normal liver function. Bleeding episodes were reported in 2.3% of the patients. A fatal gastrointestinal hemorrhage associated with thrombocytopenia was reported in one patient. Three breast cancer patients with severe liver impairment (bilirubin >1.7 times ULN) developed fatal gastrointestinal bleeding associated with severe drug induced thrombocytopenia.

Hypersensitivity Reaction: Hypersensitivity reactions requiring discontinuation of the docetaxel infusion were reported in 5 patients of 1260 who did not receive premedication. Severe hypersensitivity reactions characterized by hypotension and / or bronchospasm, or generalized rash / erythemas have been observed in only 0.9% of patients with normal liver function receiving the recommended premedication regimen and none of these patients had to discontinue therapy.

Minor events, including flushing, rash with or without pruritis, chest tightness, back pain, dyspnea, drug fever, or chills, have been reported and resolved after discontinuing the infusion and appropriate therapy.

Fluid Retention: Events such as edema and weight gain and, less frequently, pleural effusion, pericardial effusion or ascites have been described. Among 229 patients with normal liver function receiving the recommended pretreatment, severe fluid retention was observed in 6%, causing treatment discontinuation in 1.7%. When it occurs, peripheral edema usually starts at the lower extremities and may become generalized with a median weight gain of 2 kg. Fluid retention is cumulative in incidence and severity. The median cumulative dose to onset of moderate or severe fluid retention was 705 mg/m^2 . Fluid retention was completely reversible, resolving a median of 29 weeks (range : 0 to 42 + weeks) from the last docetaxel infusion.

Cutaneous: Reversible cutaneous reactions characterized by a rash including localized eruptions, mainly on the feet and / or hands, but also on the arms, face or thorax, usually associated with pruritis, have been observed. Eruptions generally occurred within one week after docetaxel infusion, recovered before the next infusion and were not disabling. Severe symptoms, such as eruptions followed by desquamation, occurred in 5.6% of the patients and rarely led to interruption or discontinuation of docetaxel treatment. Alopecia occurred in 80% of patients, and it was severe in 61.8% of patients.

Severe nail disorders occurred in 2.6% of the patients. These reactions were characterized by hypo- or hyperpigmentation, and occasionally by onycholysis (in 0.8% of patients) and pain.

Neurologic: Neurosensory symptoms characterized by paresthesia, dysesthesia or pain (including burning sensation) have been reported in patients receiving docetaxel. Severe reactions were observed in 3.9%. Neuromotor events characterized mainly by weakness have been reported and were severe in 3.7% of the patients.

Gastrointestinal : Gastrointestinal reactions (nausea, and / or vomiting, and / or diarrhoea) were generally mild to moderate and severe reactions occurred in 8.2% of the patients. Stomatitis was reported in 42.3% of patients receiving docetaxel. Severe reactions were observed in 5.3% of patients.

Cardiovascular: Hypertension occurred in 3.6% of the patients, 3.4% required treatment. Clinically meaningful events such as heart failure, sinus tachycardia, atrial flutter, dysrhythmia, unstable angina, pulmonary edema, and hypertension occurred rarely.

Infusion Site Reaction: Infusion site reactions were generally mild and consisted of Hyperpigmentation, inflammation, redness or dryness of the skin, phlebitis, extravasation, or swelling of the vein.

Hepatic: In patients with normal LFTs at baseline, bilirubin values greater than the ULN occurred in 8.9% of patients. Increase in SGOT or SGPT >1.5 times the ULN, or alkaline phosphatase >2.5 times ULN, were observed in 18.1% and 7.6% of patients, respectively. During the study, increases in SGOT and/ or SGPT >1.5 times ULN concomitant with alkaline phosphatase >2.5 times ULN occurred in 4.5% of patients with normal LFTs at baseline. (Whether these changes were related to the drug or underlying disease has not been established.)

OVERDOSAGE:

There is no known antidote for docetaxel overdosage. In case of overdosage, the patient should be kept in a specialized unit where vital functions can be closely monitored. Anticipated complications of overdosage include: bone marrow suppression, peripheral neurotoxicity, and mucositis.

There are two reports of overdose. One patient received 150 mg/m^2 and the other received 200 mg/m^2 as one hour infusions. Both patients experienced severe neutropenia, mild asthena, cutaneous reactions, and mild paresthesia and recovered without incident. In mice, lethality was observed following single I.V. doses that were >154 mg/kg (about 4.5 times the recommended human dose on a mg/m^2 basis); neurotoxicity associated with paralysis, non-extension of hind limbs and myelin degeneration was observed in mice at 48 mg/kg (about 1.5 times the recommended human dose on a mg/m^2 basis) in male and female rats, lethality was observed at a dose of 20 mg/kg . (Comparable to the recommended human dose on a mg/m^2 basis) and was associated with abnormal mitosis and necrosis of multiple organs.

DOSAGE AND ADMINISTRATION:

ADOXI

For treatment of patients with locally advanced or metastatic carcinoma of the breast after progression during anthracycline-based therapy for metastatic disease or relapse during anthracycline-based adjuvant therapy, the recommended dose of ADOXI is 60-100 mg/m² administered intravenously over one hour every three weeks.

For treatment of patients with advanced or metastatic non-small cell lung cancer after the failure of prior platinum containing therapy, the recommended dose of docetaxel is 75-100 mg/m² I.V. over one hour every 3 weeks.

Premedication Regimen : All patients should be premedicated with oral corticosteroids such as dexamethasone 26 mg. per day (e.g. 8 mg. Bid) for 5 days starting 1 day prior to ADOXI administration in order to reduce the incidence and severity of fluid retention as well as the severity of hypersensitivity reactions.

Dosage Adjustments During Treatment : Patients who are dosed initially at 100 mg/m² and who experience either febrile neutropenia (neutrophils < 500 cells/mm³), severe or cumulative cutaneous reactions, or severe peripheral neuropathy during therapy should have the dosage adjusted from 100 mg/m² to 75 mg/m². If the patient continues to experience these reactions the dosage should either be decreased from 75 mg/m² to 55 mg/m² or the treatment should be discontinued. Conversely, patients who are dosed initially at 60 mg/m² and do not experience febrile neutropenia, neutrophils < 500/mm³ for more than one week, severe or cumulative cutaneous reactions or severe peripheral neuropathy during docetaxel therapy may tolerate higher doses.

Preparation and Reconstitution of Injection.

Preparation of the Premix solution: docetaxel Concentrate IP require dilution prior to use. A sterile, non-pyrogenic, single dose diluent containing 13% w/v alcohol IP in water for Injections IP is supplied for that purpose. Remove the appropriate number of vials of docetaxel Concentrate IP from the refrigerator. Allow the vials to stand at room temperature for approximately 5 minutes. Using a syringe fitted with a needle, aseptically withdraw the entire contents of the Solvent for docetaxel Concentrate IP vial and gently transfer it to the corresponding vial of docetaxel Concentrate IP (i.e. 9.9 ml + 5% for ADOXI-120; 7.33 ml + 5% for ADOXI-80; 1.83 ml + 5% ADOXI - 20) This will assure a minimal extractable volume of 12 ml. (for ADOXI-120) or 8 ml. (For ADOXI-80) or 2 ml (for ADOXI -20) of the premix solution containing 10 mg. Docetaxel / ml. For example, a patient requiring a dose of 140 mg. Docetaxel would require 14 ml. premix solution.

Preparation of the infusion solution: Aseptically withdraw the required amount of ADOXI premix solution (10 mg. docetaxel/ml) with a calibrated syringe and inject the required volume of premix solution into a 150 ml. infusion bag or bottle of either, Sodium Chloride Intravenous infusion IP or Dextrose Intravenous infusion USP to produce a final concentration of 0.9 mg/ml.

1) If dose greater than 240 mg. of Docetaxel is required use a larger volume of the infusion vehicle so that a concentration of 0.9 mg./ml Docetaxel is not exceeded.

2) Thoroughly mix the infusion by manual rotation.

3) As with all products, ADOXI should be inspected visually for particulate matter or discoloration prior to administration whenever the solution and container permit. If ADOXI Injection premix solution or infusion solution is not clear or appears to have precipitation, the solution should be discarded. ADOXI infusion solution should be administered intravenously as a one -hour infusion under ambient room temperature and light conditions contact of the undiluted concentrate with plasticized PVC equipment or devices used to prepare solutions for infusion is not recommended. In order to minimize patient exposure to the plasticizer DEHP (di-2-ethylhexyl phthalate), which may be leached from PVC infusion bags or sets, diluted ADOXI solution should be stored in bottle (glass, polypropylene) or plastic bags (polypropylene, polyolefin) and administered through polyethylene-lined administration.

PRESENTATION :

ADOXI-20mg

Carton containing a single-dose Docetaxel Concentrate IP 20mg/vial

Carton containing Solvent for Docetaxel Concentrate IP 1.5 ml.

ADOXI-80mg

Carton containing a single-dose Docetaxel Concentrate IP 80 mg/vial.

Carton containing Solvent for Docetaxel Concentrate IP 6 ml.

ADOXI-120mg

Carton containing a single-dose Docetaxel Concentrate IP 120 mg/vial.

Carton containing Solvent for Docetaxel Concentrate IP 9 ml.

STORAGE:

The unopened vials should be stored under refrigeration at a temperature of 2-8° C (36-46° F) and should be protected from light. Freezing dose not adversely affect the product.

Solvent for Docetaxel Concentrate IP should be stored below 25°C. Protected from light. ADOXI premix solution (10 mg Docetaxel / ml) and fully prepared ADOXI infusion solution (in either sodium Chloride Intravenous Infusion IP or Dextrose Intravenous IP) should be used as soon as possible after preparation. However, the premix solution is stable for 8 hours either at room temperature, 15° to 25° C (59° to 77° F), or stored refrigerated, 2° to 8° C (36° to 46° F)

WARNING:

To be sold by retail on the prescription of a cancer specialist / cancer Hospital and institution only
Keep out of reach of children.

HANDLING : ADOXI is a cytotoxic anticancer drug and as with other potentially toxic compounds, caution should be exercised when handling and preparing ADOXI solutions. The use of gloves is recommended. If ADOXI concentrate, premix solution, or infusion come into contact with the skin or mucosa immediately and thoroughly wash with soap and water.

References

1. Seminars in Oncology Apr 1998 ; 25 suppl 3
2. Seminars in Oncology Dec 1998; 25 suppl 13.
3. JAMA 1985; 253 (11): 1033-49. Updated May 1999
4. PDR 1998 : 52ND EDITION : 2385-89.

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