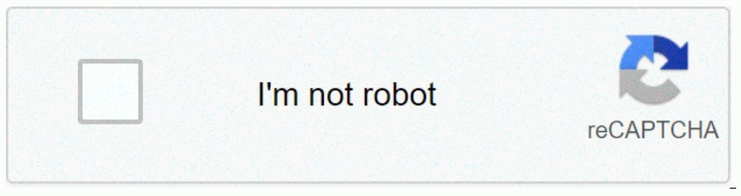


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Kwiring C, Sanoski CA, Valleran. Cyclophosphamide. Davis' guide to drugs. F.A. Davis Company; 2020 . Access to December 20, 2020. Cyclophosphamide. Davis's guide to drugs (16th edition). F.A. Davis's company. Received on December 20, 2020 from C, Sanoski CA, Vallerand AH. Cyclophospamid (Internet). In: Davis' guide to drugs. F.A. Davis Company; 2020. Cited 2020 December 20. Available from: . AU - Sanoski, Cynthia A, AU - Vallerand, April Hazard, BT - Davis Drug Guide UR - PB - F.A. Davis Company ET - 16 DB - Anesthesia Central DP - Non-Emergency Medicine ER - Dosage Form: Tablet Medically Examined Drugs.com. Last updated on August 1, 2020. Indications and use for cyclophospamide malignant diseases cyclophospamid shown for treatment: malignant lymphomas (stages III and IV of the staging system ann-Arbor), Hodgkin's disease, lymphocytic lymphoma (node or diffuse), mixed-type lymphoma, histocyte lymphoma, Burkitt lymphoma - multiple myeloma and leukemia: chronic lymphocytic leukemia. chronic granulocytic leukemia (it is usually ineffective in acute blissful crisis), acute myelogous and monocytic leukemia, acute lymphoblastic (stem) leukemia (cyclophosphamid given during remission) - adenocarcinoma breast carcinoma cyclophosphamide, although effective only in susceptible malignancies, is more often used simultaneously or consistently with other antineoplastic drugs. Minimum change in nephrotic syndrome in pediatric patients: Cyclophospide tablets shown to treat biopsies have proven minimal variation of nephrotic syndrome in pediatric patients who have failed to respond adequately or are unable to tolerate adrenocorticosteroid therapy. Restrictions on use: The safety and efficacy of cyclophospide tablets for the treatment of nephrotic syndrome in adults or other kidney diseases has not been established. Cyclophospide Dosage and Administration Hydration and important administration instructions during or immediately after the introduction of the cyclophospide tablet, sufficient amounts of fluid should be swallowed or infused into the virtue of diuresis in order to reduce the risk of urinary tract toxicity. Therefore, cyclophospide tablets should be taken in the morning. Cyclophospide tablets should be swallowed whole. Tablets should not be chewed or shredded. Cyclophospamine tablets cytotoxic drug. Follow the applicable special treatment and removal procedures.1 Avoid exposure to broken tablets. When in contact with broken tablets immediately and thoroughly wash your hands. The recommended dose for malignant diseases of adults and pediatric patients The recommended dose of cyclophospide tablets is in the range of 1 mg per kg to 5 mg per kg orally once a day for initial and maintenance dosing. Other oral cyclophospamine schemes have been reported. Dosages should be adjusted based on evidence of antitumor activity, myelosuppression or other severe adverse reactions (see Warnings and Precautions (5)). It may be necessary to reduce the dose of cyclophospamine as well as other drugs. The recommended dose for minimal change of nephrotic syndrome in pediatric patients The recommended dose of cyclophospide tablets is 2 mg per kg once a day for 8 to 12 weeks (maximum cumulative dose of 168 mg per kg). infertility in men (see Use in specific populations (8.4), Dosage Of Shape and Strong Tablets: 25 mg cyclophospide, USP. The tablets are white with blue spots and printed with 25 on one side and BXT on the other. 50 mg of cyclophospide, USP. Tablets are white with blue spots and printed with 50 on one hand and BXT on the other. Anaphylactic reactions, including death have been reported with cyclophosphi murder.)Warnings and precautions of myelosuppression, immunosuppression, bone marrow failure and cyclophospide infections can cause myelosuppression (leukopenia, neutropenia, thrombocytopenia and anemia) , bone marrow failure, and severe immunosuppression, which can lead to serious and sometimes fatal infections, including sepsis and septic shock. Hidden infections can be reactivated (see Adverse Reactions (6.2), Antimicrobial Prophylaxis may be shown in some cases at the discretion of the managing physician. So the dose can be adjusted if necessary. Cyclophosphiamide should not be administered to patients with neutrophils ≤1500/mm3 and platelets of 50,000/mm3. Cyclophospide treatment cannot be indicated, or should be interrupted, or dose reduced, in patients who have or who develop a serious infection. G-CSF can be introduced to reduce the risk of neutropenia complications associated with the use of cyclophospide. Primary and secondary prevention with G-CSF should be considered in all patients who are considered to have an increased risk of complications of neutropenia. Nadir reductions in the number of white blood cells and platelets are usually achieved during week 1 and 2 of treatment. It is believed that the number of peripheral blood cells will normalize after about 20 days. Bone marrow failure was reported. Severe myelosuppression can be expected especially in patients who have previously received and/or receive concomitant chemotherapy and/or radiation therapy. Urinary tract and renal toxicity hemorrhagic cystitis, pielite, ureter, and hematuria have been reported with cyclophosphamide. Medical and/or surgical supportive treatment may be required to treat protracted cases of severe hemorrhagic cystitis. Stop cyclophosphomid therapy in case of severe hemorrhagic cystitis. Urotoxicity (ulcer bladder, necrosis, fibrosis, contracture and secondary may require discontinuation of cyclophosphidal or cystectomy. Urototoxicity can be fatal. Urototoxicity may occur with short- or long-term use of cyclophosphamide. Before starting treatment, exclude or correct any urinary tract obstruction (see contraindications (4). Cyclophosphamide should be used with caution, if at all, in patients with active urinary tract infections. Aggressive hydration with forced diuretic and frequent bladder emptying can reduce the frequency and severity of bladder toxicity. miopericcarditis, pericardial effusion, including cardiac tamponade, and congestive heart failure, which can be fatal, have been reported with Supraventricular arrhythmia therapy (including atrial fibrillation Ritter) and ventricular arrhythmia (including severe prolongation of ST associated with ventricular tachiarhythmia) have been reported after treatment The risk of cardiotoxicity can be increased with high doses of cyclophospamine , in patients with advanced age, as well as in patients with previous radiation therapy in the heart and/or previous or related treatment by other cardiotoxic agents. Particular care is needed for patients with risk factors of cardiovascular failure and patients with pre-existing heart disease. Monitoring patients with cardiovascular risk factors and pre-existing heart disease. Pulmonary pneumonitis toxicity, pulmonary fibrosis, pulmonary venocfulcic disease and other forms of pulmonary toxicity leading to respiratory failure were reported during and after treatment with cyclophosphimide. Late pneumonitis (more than 6 months after the onset of cyclophosphamide) appears to be associated with an increase in mortality. Pneumonitis can develop years after treatment with cyclophosphomeyd. Monitoring patients for signs and symptoms of pulmonary toxicity. Secondary malignancies cyclophospide genotoxic (see Nonclinical Toxicology (13,1). lymphomas, thyroid cancer and sarcoma) have been reported in patients treating cyclophosphomids-containing regimens. in preparation for bone marrow transplantation, which consists of cyclophosphamide combined with full-body irradiation, beusulfan or other agents. VOD is also it is reported to gradually develop in patients receiving long-term low doses of immunosuppressive doses of cyclophospamine. Other risk factors predisposing to THE development of VOD include pre-existing liver dysfunction, previous abdominal radiation therapy, and poor performance status. Embryo-fetal toxicity Based on its mechanism of action and published reports on the effects on pregnant patients or animals, Cyclophospide tablets can harm the fetus when administered to a pregnant woman (see. Use in specific populations (8.1), Clinical Pharmacology (12.1), and nonclinical toxicology (13.1). Rats, rabbits and monkeys. Advising pregnant women and women of reproductive potential is a potential risk to the fetus (see Use in specific populations (8.1)Check the status of women's pregnancy reproductive potential prior to the onset of cyclophosphomid pills. I advise women of reproductive capacity to use effective contraception during treatment with cyclophosphid tablets and for up to 1 year after the end of therapy. , 8.3)». Infertility of male and female reproductive function and fertility may be impaired in patients treated with cyclophosphomid tablets. Cyclophospide interferes with oogenesis and spermatogenesis. This can cause infertility in both sexes. The development of infertility appears to depend on the dose of cyclophospamid, the duration of therapy, and the condition of gonadal function during treatment. Cyclophosphamide induced sterility may be irreversible in some patients. Advising patients about the potential risks of infertility (see Use in specific populations (8.3, 8.4)Breaking the wound Healing cyclophospide can interfere with normal wound healing. Hyponatremia hyponatremia associated with increased total water volume in the body, acute water intoxication and syndrome resembling SIADH (an inappropriate secretion of the antidiuretic hormone) that can be fatal, has been reported. , Immunosuppression, bone marrow failure and infection (see Warnings and Precautions (5.1) - Such warnings and renal toxicity (see Warnings and Precautions (5.2) and Precautions (5.5) - Veno-occlusion liver disease (see Warnings and Precautions (5,6) - Infertility (see. Warnings and precautions (5.8) and use in specific populations (8.3, 8.4) . The degree of neutropenia is particularly important because it correlates with reduced resistance to infections. There are separate reports of haemorrhagic colitis, oral mucous ulcers and jaundice occurring during therapy. Skin and its structure: Alopecia occurs in patients treated with cyclophosphamide. , accurate frequency estimates cannot be made. Cardiac: cardiac arrest, ventricular fibrillation, ventricular tachycardia, cardiogenic shock, perycardial effusion (progresses to cardiac tamponade), myocardial hemorrhage, myocardial infarction, heart failure (including fatalities), cardiomyopathy, cardiomyopathy, myocarditis, pericarditis, carditis, atrial fibrillation, supraventricular arrhythmia, ventricular arrhythmia, bradycardia, bradycardia, congenital, family and genetic: intrauterine death, fetal malformation, fetal growth delay, fetal toxicity (including myelosusia). Ear and labyrinth: deafness, hearing impairment, tinnitus. Endocrine: water intoxication. Eye: visual impairment, conjunctivitis, lacrimation. gastrointestinal: gastrointestinal hemorrhage, acute pancreatitis, colitis, enteritis, setsitis, stomatitis, constipation, inflammation of the parotid glands. General disorders and administrative conditions of the site: multiorganic failures, general physical deterioration, flu-like diseases, injectable/infusion reactions of the site (thrombosis, necrosis, phlebitis, inflammation, pain, swelling, erythema), pyrexia, swelling, chest pain, mucosion inflammation, asthenia, pain, chills, fatigue, ailment. Hematological: myelosuppression, bone marrow deficiency, common intravascular coagulation and hemolytic uremic syndrome (with thrombotic microangiopathy). hepatic: venoclusive liver disease, cholestatic hepatitis, cytolytic hepatitis, hepatitis, cholestasis; hepatotoxicity with liver failure, hepatic encephalopathy, ascites, blood bilirubin increased, hepatic function abnormal, liver enzymes increased. Immunity: immunosuppression, anaphylactic shock and hypersensitivity response. Infections: The following manifestations have been associated with myelosuppression and immunosuppression caused by cyclophospide: increased risk and severity of pneumonia (including deaths), other bacterial, fungal, viral, protozoa and parasitic infections; reactivation of hidden infections (including viral hepatitis, tuberculosis), geerovechi pneumocystis, herpes shingles, silyloids, sepsis and septic shock. Studies: Lactat blood dehydrogenase increased, C-reactive protein increased. Metabolism and nutrition: hyponatreemia, fluid retention, increased blood glucose levels, decreased blood glucose levels. Muscle-connective tissue: rhabdomyolysis, scleroderma, muscle spasms, myalgia, artralgia. Neoplasma: acute leukemia, myelodysplastic syndrome, lymphoma, sarcoma, renal cell carcinoma, kidney cancer, bladder cancer, ureter, thyroid cancer. Nervous system: encephalopathy, convulsions, dizziness, neurotoxicity has been reported and manifested as reversible syndrome of posterior

leukoencephalopathy, myelopathy, peripheral neuropathy, polyneuropathy, neuralgia, dysthesia, hypoesthesia, paresthesia, tremor, dysgeusia, hypogeusia, parosomy. Pregnancy: preterm birth. Psychiatric: a mess of the condition. Renal and urinary system: renal failure, renal tubular disorder, renal disorders, nephropathy toxic, hemorrhagic cystitis, bladder necrosis, ulcerative cystitis, bladder contracture, hematology, nephrogenic diabetes, atypical epithelial bladder. Reproductive system: infertility, ovarian insufficiency, ovarian disorder, amenorrhea, oligomonorrhea, testicular atrophy, azoospermia, oligospermia. Respiratory: pulmonary venoclusive disease, acute respiratory distress syndrome, interstitial lung disease, manifested respiratory failure (including fatalities), obliteral bronchiolitis, organizing pneumonia, allergic alveolith, pneumitis, pneumonia, pneumonia, pulmonary hemorrhage; respiratory failure, pulmonary hypertension, pulmonary swelling, pleural effusion, bronchospasm, shortness of breath, hypoxia, cough, nasal congestion, nose discomfort, throat pain, rhinorrey. Skin and subcutaneous tissue: toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiform, palmar-plantar erythroditesia syndrome, radiation dermatitis, toxic skin eruption, hives, dermatitis, blister, itching, erectile, nail disorder, facial swelling, hyperhidrosis. Tumor lys syndrome: Like other cytotoxic drugs, cyclophosphamide can cause tumor lysion syndrome and hyperuricemia in patients with fast-growing Vascular: pulmonary embolism, venous thrombosis, vasculitis, peripheral ischemia, hypertension, hypotension, flushing, tide. Dealing with drug use is a pro-drug, which is activated by the P450s cytochrome (see Clinical Pharmacology (12.3), increased concentration of cytotoxic metabolites can occur with protease inhibitors: Concomitant use of protease inhibitors may increase the concentration of cytotoxic metabolites. receiving cyclophosphidal, doxorubicin and ethoposide (CDE) than the use of non-Nucleoside reverse transcriptase inhibitor regimen. Combined or consistent use of cyclophospide and other agents with similar toxicity Increased hematotoxicity and/or immunosuppression may result from the combined effect of cyclophospamine and, for example: ACE inhibitors: ACE inhibitors can cause leukopenia. Natalizumab Paclitaxel: Increased hematotoxicity was reported when cyclophosphimid was injected after paklitaxel infusion. Thiazid diuretic sisovudin Elevated cardiotoxicity may result from the combined effect of cyclophospamid and, for example: for example: Amiodarone - G-CSF, GM-CSF (granulocytic stimulant factor of the colony, granulocyte macrophacus colony-stimulating factor): Reports indicate an increased risk of pulmonary toxicity in patients, treatment of cytotoxic chemotherapy, which includes cyclophosphamid and G-CSF or GMCSF. Increased nephrotoxicity may result from the combined effect of cyclophosphamide and, for example: Amphotericin B Indomethacin: Acute water intoxication has been reported with the associated use of indomethacin Increase in other toxicities: Azatioprine: Increased risk of hepats Carotoxicity (liver necrosis) Busulfan: Increased incidence of hepatic veno- Protease inhibitors: Increased incidence of mucositis Increased risk of hemorrhagic cystitis may result from the combined effect of cyclophospamine and past or concomitant radiation therapy. Etanercept: In patients with wegener's granulomatosis, the addition of ethanolcept to standard treatment, including cyclophospide, was associated with a higher incidence of uncut malignant solid tumors. Metronidazole: Acute encephalopathy was reported in a patient receiving cyclophosphosfamid and metronidazole. The cause-and-effect relationship is unclear. In an animal study, a combination of cyclophosphamide with metronidazole was associated with increased toxicity of cyclophosphamide. Tamoxifen: The concomitant use of tamoxifen and chemotherapy may increase the risk of thromboembolic complications. Coumarins: How increased and reduced warfarin effect has been reported in patients warfarin and cyclophospide. Cyclosporine: Lower serum cyclosporine concentrations were observed in patients receiving a combination of cyclophospamine and cyclosporine than patients receiving only cyclosporine. This interaction can lead to an increase in the incidence of graft compared to the host disease. Depolarization of muscle relaxants: Treatment of cyclophosphamid causes noticeable and persistent inhibition of cholinsterase activity. Long-term apnea can occur with the simultaneous depolarization of muscle relaxants (e.g. succinoline). If the patient was treated with cyclophospamidom within 10 days of general anesthesia, alert the anesthesiologist. USE IN SPECIFIC POPULATIONS Pregnancy Risk Summary Based on its mechanism of action and published reports on the impact on pregnant patients or animals, Cyclophospamid tablets can harm the fetus when administered to a pregnant woman (see Clinical Pharmacology (12.1) and non-clinical toxicology (13.1). Rats, rabbits and monkeys. Advising pregnant women and women of reproductive potential is a potential risk to the fetus. The estimated background risk of serious birth defects and miscarriages for the population in question is unknown. In the general U.S. population, the background risk of major birth defects is estimated to be 2%-4% and miscarriage is 15%-20% of clinically recognized pregnancies. Human data of human malformations of the skeleton, palat, limbs and eyes, as well as miscarriage were recorded after exposure to cyclophosphamid in the first trimester. Fetal stunting and toxic effects are evident in newborns, including leukopenia, anemia, pancytopenia, severe bone marrow hypoplasia, and gastroenteritis have been reported after exposure to cyclophosphamid. The management of animal data cyclophosphamide for pregnant mice, rats, rabbits and monkeys during organogenesis in doses or lower doses in patients based on the area of the body surface led to various malformations that included neural tube defects, limbs and numbers of defects and other skeletal abnormalities, cleft lip and palate, and reduced skalaification. Lactation Risk Summary cyclophosphamide is present in breast milk. Neutropenia, thrombocytopenia, low haemoglobin, and diarrhea have been reported in infants breastfed by women treated with cyclophospide. Due to the possibility of serious adverse reactions in infants from cyclophospamid, it is advised to breast-feed women during treatment and for 1 week after the last dose. Females and male reproductive potential pregnancy testing check pregnancy status reproductive potential before the start of the The pill (see use in specific populations (8.1)Women's contraception cyclophospide can harm the fetus. Advising women of reproductive potential for effective contraception during treatment with cyclophospamid tablets and for up to 1 year after the end of therapy (see use in specific populations (8.1). advise male patients with female partners of reproductive potential to use effective contraception during treatment with cyclophosphosphamide tablets and for at least 4 months after the completion of therapy (see Use in specific populations (8.1) and non-clinical toxicology (13.1)). Associated with reduced estrogen and increased secretion of gonadotropin develops in proportion of women treated with cyclophosphamide. that the increased risk of botched pregnancies and malformations may persist after cyclophosphanide is discontinued as long as there are oocytes/follicles exposed to cyclophospamid at any stage of maturation. The exact duration of follicular development in humans is unknown, but may be more than 12 months (see Nonclinical Toxicology (13.1). which are usually associated with an increase in gonadotropin, but normal testosterone secretion. Pediatric use of pre-pubescent girls treated with cyclophosphamide generally develops secondary sexual characteristics normally and has regular menses. ovarian fibrosis with apparent total loss of germ cells after long-term treatment of cyclophosmide at the end of pre-puberty has been reported. Prepubertate boys treated with cyclophosphamide develop secondary sexual characteristics normally, but may have oligospermia or azoospermia and increased secretion of gonadotropin. Cyclophosphamide-induced azoospermia is reversible in some patients, although reversibility may not occur for several years after discontinuation of therapy. to determine if they react differently than younger patients. Overall, the choice of dose for an elderly patient should be careful, usually starting with a low-end dosing range, reflecting a greater frequency of decrease in hepatic, renal, or or as well as comorbidities or other drug therapy. Use in patients with renal disorders in patients with severe renal disorders, reduced kidney secretion can lead to an increase in plasma levels of cyclophospamid and its metabolites. This can lead to increased toxicity (see Clinical Pharmacology (12.3), Monitoring patients with severe renal disorders (CrCl 10 ml/min to 24 ml/min) for signs and symptoms of toxicity. Cyclophospamid and its metabolites are anonymized, although there are probably quantitative differences depending on the dialysis system used. The use in patients with hepatic disorders in patients with severe hepatic disorders reduced the conversion of cyclophospide into active 4-hydroxyl metabolitis, potentially reducing the effectiveness of see Clinical Pharmacology (12.3). Overdose should be administered with supportive measures, including appropriate treatment for any simultaneous infection, myelosuppression, or cardiac toxicity if this happens. such as myelosuppression, uretoxicity, cardiotoxicity (including heart failure), veno-occlusion liver disease, and stomatitis (see Warnings and precautions (5.1, 5.2, 5.3, and 5.6) Cyclophosphamide and its metabolites are anonymized. Chemical name cyclophosphamide 2-Bis (2-chloroethyl)aminoetrahydro-2H-1,3,2-oxasphosphorin 2-oxide monohydrate, and has the following structural formula: Cyclophosphamed has a molecular formula C7H15Cl2N2O2P H2O and molecular 27 Cyclof soluble in water, salt or ethanol. Cyclophospide tablets USP for oral use and contain 25 mg or 50 mg of cyclophospide (anhydrous). Inactive ingredients in cyclophospamid tablets are: acacia, FD-C Blue No 1, DSK yellow lake No. 10 Aluminum Lake, lactose, magnesium stearat, starch, steaic acid and talc. Cyclophospide - Clinical Pharmacological Action Mechanism Mechanism is thought to include cross-binding tumor cells. Pharmacodynamics cyclophospamide biotransformed mainly in the liver to active alkylatin metabolites mixed function of microsomal oxidase oxidase These metabolites interfere with the growth of susceptible rapidly multiplying malignant cells. Pharmacokinetics Absorption After oral administration, peak concentrations of cyclophospamine occurred at one hour. The area on the drug's post-oral and IV injection curve (AUCpo : AUCiv) ranged from 0.87 to 0.96. The distribution of approximately 20% of cyclophosphimid protein is associated, without a dose of dependent changes. Some metabolites are protein-related to a degree greater than 60%. The distribution is approaching the total water of the body (30 to 50 liters). Liver metabolism is the main place of activation of cyclophosphid. Approximately 75% of the injected dose of cyclophospamine is activated by hepatic microsomal cytochrome P450s, including CYP2A6, 2B6, 3A4, 3A5, 2C9, 2C18 and 2C19, with 2B6 display of the highest 4-hydroxylase activity. Cyclophosphamide is activated to form 4-hydroxycyclophosphamid, which is in balance with its open ring tautomer aldophosphamide. 4-hydroxyCyclophosphosphamide and Aldophosphamide may be exposed to oxidation by aldehyde dehydrogenases to form inactive metabolites 4-ketoCyclophosphospamid and carboxyphosphamide, respectively. Aldophosphamide can pass β to form active metabolites of phosphoramethide mustard and acroline. This spontaneous transformation can be catalisin albumin and other proteins. Less than 5% of cyclophosphate can be directly detoxifying the lateral chain of oxidation, leading to the formation of inactive metabolites 2-dechloroethylCyclophosphamide. At high doses, the proportion of the parent compound purified by 4-hydroxylation decreases, leading to non-linear elimination of cyclophosphidal in patients. Cyclophospamid seems to induce its own metabolism. Autoinduction leads to an increase in the total clearance, an increase in the formation of 4-hydroxyl metabolites and shortened values of t1/2 after re-introduction at intervals of 12 to 24 hours. Elimination of cyclophospide is primarily singled out as metabolites. From 10 to 20% is excreted unchanged in the urine and 4% is excreted in bile after the introduction of IV. Special populations of renal disorders Pharmacokinetics cyclophospamid were determined after one hour of intravenous infusion for patients with renatal disorders. The results showed that the systemic impact of cyclophospamine increased as the kidney function decreased. The average dose of adjusted AUC increased by 38% in the moderate renal group, (Creatinine clearance (CrCl 25 to 50 ml/min), by 64% in the severe renal group (CrCl 10 to 24 ml/min) and by 23% in the hemodialysis group (CrCl qlt; 10 ml/min) compared to the control group. in four patients with long-term hemodialysis. Dialysis clearance, calculated on arterial-venosis difference and actual recovery of the drug in dialysis, on average is 104 ml/min, which is in the range of metabolic clearance 95 ml/min for the drug. On average, 37% of the injected dose of cyclophosphidal was removed during hemodialysis. Elimination of the half-month period (t1/2) was 3.3 hours in patients during hemodialysis, a 49% decrease of 6.5 hours to t1/2 reported in uremic patients. Reduction of t1/2, greater dialysis clearance than metabolic clearance, high extraction efficiency and significant removal of the drug during dialysis, indicate that cyclophosphamide is dialyzable. Liver disorder General body clearance (CL) cyclophospamid decreases by 40% in patients with severe hepatic disorders and elimination of the half-rid period (t1/2) is extended by 64%. Average CL and t1/2 were 45 ± 8.6 l/kg and 12.5 ± 1.0 hours respectively, in patients with severe liver disorders and 63 ± 7.6 l/kg and 7.6 ± 1.4 hours respectively in the control group use in specific populations (8.7). Non-clinical toxicological carcinogenesis, mutagenes, fertility disorders cyclophospamid, administered by various routes, including intravenous, subcutaneous or intra-peritoneal injections, or in drinking water, caused tumors in mice and rats. In addition to leukemia and lymphoma, benign and malignant tumors have been found in various areas of tissue, including bladder, breast, lungs, liver and injection site (see. Warnings and precautions (5,5)Cyclophosphamid has been mutagenic and xlastogenic in several studies in vitro and vivo genetic toxicology. Cyclophosphamid is genotoxic in male and female germ cells. and the increased risk of malformations. male mice and rats treated with cyclophospemia, there are changes in male reproductive organs (e.g., weight loss, atrophy, changes in spermatogenesis), as well as reduced reproductive potential (e.g., reduced implantation and increased loss after implantation) and increased fetal malformations when mating with untreated females (see use in specific populations). OSHA Dangerous Drugs. Osha. . How to supplied/Storage and processing tablets: 25 mg cyclophospamid, USP. The tablets are white with blue spots and are imprinted with 25 on one side and BXT on the other. NDC 10019-982-01: Boxes containing a bottle of 100 tablets (NDC 10019-982-09) - 50 mg cyclophospide, USP. The tablets are white with blue spots and imprinted with 50 s side and BXT on the other side. NDC 10019-984-01: Boxes containing a bottle of 100 tablets (NDC 10019-984-09) Store tablets at 20 degrees Celsius to 25 degrees Celsius up to 77 degrees Fahrenheit); Excursions are allowed between 15 and 30 degrees Celsius (59 to 86 degrees Fahrenheit) (see USP Controlled room temperature). Cyclophospamid is an antineoplastic product. Follow special treatment and removal procedures.1 Patient Counseling Information Patient Advice as follows: Myelosuppression, Immunosuppression, and Infections - Notify patients of the possibility of myelosuppression, immunosuppression and infections. Explain the need for the usual counting of blood cells. Instruct patients to frequently monitor the temperature and immediately report any occurrence of fever (see Warnings and precautions (5.1). urinary tract and renal toxicity - Advise the patient to report symptoms of the urinary tract (patients should report, if their urine has become pink or red) and the need for increased fluid intake and frequent cancellation (see Warnings and precautions (5.2)Cardiotoxicity - Advise patients to seek immediate medical attention for any of the following: new onset or deterioration of shortness of breath, cough, swelling of the ankle/legs, rapid heartbeat, weight gain of more than 5 pounds within 24 hours, dizziness or loss of consciousness (see Warnings and Precautions (5.3)Pulmonary Toxicity - Warn patients of the possibility of developing noncommunicable pneumonants. and Precautions (5.4)Embrio-fetal toxicity - Inform patients about the risk to the fetus and potential loss of pregnancy. 8,1)». Advising women patients of reproductive potential on the use of effective contraception during treatment and within 1 year after the end of therapy (see Warnings and Precautions (5.7) and Use in Specific Populations (8.1, 8.3), Advising male patients with female partners of reproductive capacity to use effective contraception during treatment and for up to 4 months after the end of therapy (see Warnings and Precautions (5.7) and use in specific populations (8,1, 8.3)Lactation and counseling of breastfeeding women not to breastfeed during treatment and within 1 week after the last dose of cyclophospide (see Use in specific populations (8.2), infertility and cyclophospamine pills can worsen fertility in both men and women's reproductive potential (see Warnings and Precautions (5.8) and Use in Specific Populations (8.3.3) , 8,4) ». Common adverse reactions - patients that side effects such as nausea, vomiting, stomatitis, wound healing disorder, amenorrhea, premature menopause, infertility and hair loss may be associated with the administration of cyclophospide. Other undesirable effects (such as dizziness, blurred vision, visual impairment) may affect the ability to drive or use (see Adverse Reactions (6.1, 6.2)Hydration and Important Administration Instructions - Tell the patient that during or immediately after administration, enough fluid is needed to reduce the risk of urinary tract toxicity (see Dosage and Administration (2.1) or crush pills (see Dosage and Administration (2.1) . Advise caregivers to wear gloves when handling bottles containing cyclophospide tablets, and avoid exposure to broken tablets. The German Buckster Product is a registered trademark of Baxter International Inc. HA-30-01-863 Revised August 2020 PACKAGE/LABEL PRINCIPAL DISPLAY PANEL LABEL Barcode 100 tablet NDC 10019-982-09 Cyclophosphamide tablets USP 25 mg CYTOTOXIC AGENT Wear gloves when processing container and tablet rx only Baxter Logo Manufactured for Baxter Healthcare Corporation Deerfield, IL 60015 U.S. Made in Italy Product Germany Each tablet contains 25 mg cyclophospide, USP. Recommended dosage: See the appointment information. Swallow the tablets whole. Don't cut, chew, or crush pills. Get around in a tight container, as defined in the USP. Store at or below 25 degrees Celsius (77 degrees Fahrenheit) (see USP Controlled room temperature). GS1-1D barcode for position only (01) GTIN US HA-65-01-744 3001068 Lot Exp. YYYY-MM Carton Label GTIN: S/N: LOT: EXP.: YYYY-MM GS1-2D Barcode for position only (01) GTIN Barcode NDC 10019-982-01 Cyclophospamid Tablets, USP 25 mg CYTOTOXIC AGENT Wear gloves when handling container and tablets 100 tablets Rx only the logo Baxter Manufactured for Baxter Healthcare Corporation Deerfield, IL 60015 U.S. Made in Italy Product Germany 3001067 CYTOTOXIC AGENT Each tablet contains 25 mg of cyclophosp, USP. Recommended dosage: See the appointment information. Swallow the tablets whole. Don't cut, chew, or crush pills. Get around in a tight container, as defined in the USP. Store at 20 to 25 degrees Celsius (68 to 77 degrees Fahrenheit) (see USP Controlled Room Temperature) HA-80-02-730 U.S. NDC 10019-982-01 Cyclophospamide Tablets, USP 25 mg CYTOTOXIC AGENT Wear gloves when handling container and tablets 100 tablets Rx only Baxter Logo Manufactured for Baxter Healthcare Corporation Deerfield, IL 60015 U.S. Made in Italy Product Germany NDC 10019-982-01 Cyclophosphamide Tablets, USP 25 mg 100 Tablets Barcode AB14 NDC 10019-982-01 Cyclophosphamide Tablets, USP 25 mg AGENT Wear gloves when processing container and tablets 100 tablets Rx only 2638B6200 Container Label Barcode 100 TABLETS NDC 10019-984-09 Cyclophospamide tablets, USP 50 mg CYTOTOXIC AGENT Wear gloves when handling container and tablet rx only Baxter logo logo for Baxter Healthcare Corporation Deerfield, IL 60015 U.S. Made in Italy Product Germany Each tablet contains 50 mg of cyclophospide, USP. Recommended dosage: See the appointment information. Swallow the tablets whole. Don't cut, chew, or crush pills. Get around in a tight container, as defined in the USP. Store at or below 25 degrees Celsius (77 degrees Fahrenheit) (see USP Controlled room temperature). GS1-1D barcode for position only (01) GTIN US HA-65-01-745 3001069 Lot Exp. YYYY-MM Carton Label GTIN: S/N: LOT: EXP.: YYYY-MM GS1-2D Barcode for position only (01) GTIN Barcode NDC 10019-984-01 Cyclophospide Tablets, USP 50 mg CYTOTOXIC AGENT Wear gloves when handling container and tablets 100 tablets Rx only the logo Baxter Manufactured for Baxter Healthcare Corporation Deerfield, IL 60015 U.S. Made in Italy Product Germany 3001066 CYTOTOXIC AGENT Each tablet contains 50 mg of cyclophosp, USP. Recommended dosage: See the appointment information. Swallow the tablets whole. Don't cut, chew, or crush pills. Get around in a tight container, as defined in the USP. Store at 20 to 25 degrees Celsius (68 to 77 degrees Fahrenheit) (see USP Controlled Room Temperature) HA-80-02-731 U.S. NDC 10019-984-01 Cyclophospamide Tablets, USP 50 mg CYTOTOXIC AGENT Wear gloves when handling container and tablets 100 tablets Rx only Baxter Logo Manufactured for Baxter Healthcare Corporation Deerfield, IL 60015 U.S. Made in Italy Product Germany NDC 10019-984-01 Cyclophospamide Tablets, USP 50 mg 100 tablets Barcode F4 NDC 10019-984-01 Cyclophospamide tablets, USP 50 mg CYTOTOXIC AGENT Wear gloves when processing container and 1 tablet 1 Rx Tablets Only 2638B6201 Cyclophospamid Cyclophospide Tablet Product Information Product Type HUMAN PRESCRIPTION LABEL Code (Source) NDC:10019-982 Route Administration ORAL DEA Schedule Active Ingredient / Moiety Ingredient Title Active Strength Cyclophosphamid (Cyclophosphamid ANHYDROUS) Cyclophospins MG Product Characteristics WHITE (White with Blue Spots) Score no score BXT;25 Contains Packaging - Code Package Description 1 NDC:10019-982-01 1 BOTTLE in 1 CARTON 1 NDC:10019-982-09 100 BOTTLE at 1 100 BOTTLE at 1 Marketing Information Marketing Category Application Number or Monograph Citation Marketing Date Start Date End date NDA authorized general NDA012141 08/07/2020 Cyclophospide Cyclophospide Tablets Product Information Product Type HUMAN PRESCRIPTION0019-984 Route Administration ORAL DEA Schedule Active Ingredient / Active Moiety Ingredient Title Strength Basics Cyclophospide (Cyclophospide ANHYDROUS) CyclophosAMIDE ANHYDROUS 50 mg Product Characteristics Color WHITE (white with blue spots) Score not score ROUND (Biconvex) Размер 11mm Flavor Imprint Code Code 1 NDC:10019-984-01 1 BOTTLE at 1 CARTON 1 NDC:10019-984-09 100 TABLET in 1 BOTTLE Marketing Information Marketing Category No. Application or Monograph Citation Marketing Start Date Marketing Date NDA NDA NDA012141 08/07/2020 Labeler - Baxter Healthcare Corporation (005083209) Baxter Healthcare Corporation Medical Disclaimer