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periode of the cutton priest protection.

FLURAC INJECTION 50 mg/ml

imu yarb haloson sa yara ndauim **(Fluorouracii Injection BP 50 mg/ml)**თინები ან არებინ 600 a. to 10 1995 - ესინინი

desora lei serge dimenti cine p. For Intravenous use only ameni de per tens bi a famo Cine i de de abolicado han

Each ml contains:

mangung verne (Cleanshermannie no heusernah) in vyracifierdud i Pluffil einnig Grubur Lieband. 🖣 Flurorouracil Ph.Eur. (as Fluorouracil Sodium)50 mg.

Water for Injections Ph. Eur.

Pharmaceutical Form Taglids (1) one fig. (14) editing visuoneyers approximately in a residence of the contraction of the contra

Solution for injection graphs above about asomative the value was added to provide a provide a provided above to a provided and the second of the second and the second and

Product Description A clear, colourless to almost colourless solution in a clear glass vial. When examined under suitable conditions of visibility it should be practically: free from particles, program a group wisers galaxies in poor mobbles accompany of the first and modernization consistency and the consistency of the formal accompany of the first and accompany of the first Description after dilution: Clear, colorless solution automorphism of any particle of the second continued and the spapers of the

Chemistry:

outratidates a librares vidit Molecular Formula: C.H.FN.Q.-Chemically: Fluorouracil, a fluorinated pyrimide, is 5-fluoro-2, 4 (1H, 3H) pyrimidinedione. It is a white to practically white crystalline powder which is sparingly soluble in waters and use appropriate the property of a contract of the contract of th Molecular Weight: 130.08

Pharmacological classifications: described in a release election of the control of the professional described in the control of the control o Antimetabolite, antineoplastic agent.

Clinical Pharmacology: a portion may be subjected as the control of the control o In this manner Flurac interferes with the synthesis of deoxyribonucleic acid (DNA) and to a lesser extent inhibits the formation of ribonucleic acid (RNA). Since DNA and RNA are essential for cell division and growth, the effect of Flurac may be to create a thymine deficiency which provokes unbalanced growth and death of the cell. The effects of DNA and RNA deprivation are most marked in those cells which grow more rapidly and which take up Flurac at a more rapid rate. Laimens inicompolipacing plansystyp kin one belongsty visa joigalousees.

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Evry et a fillig et mageotaga vair film colo unit A jun Kelandi Chumada et administratus. Puve ab tres, he critiquev e mediesiarione would

Confre associated in their analysis of both Following intravenous injection, Flurac distributes into tumors, intestinal mucosa, bone marrow, liver and other tissues throughout the body, in spite of its limited lipid solubility. Flurac diffuses readily across the blood-brain barrier and distributes into cerebrospinal fluid and brain tissue.

nushed compared form to the characteristic street with a new percent of the parent drug is excreted unchanged in the unite in six hours; of this over 90% is excreted in the first hour. The remaining percentage of the administered dose is metabolized, primarily in the liver. The catabolic metabolism of Flurac results in degradation products (eg. CO,, urea and alfa-fluoro-beta-alanine) which are inactive. The inactive metabolites are excreted in the urine over the next 3 to 4 . เรียงสราย แ**ดงอย**ากอน และกราช โดยสามารถในสมาชาก

Following intravenous administration of Flurac, the mean half-life of elimination from plasma is approximately 16 minutes, with a range of 8 to 20 minutes, and is dose dependent.

Per in season mighting disentage, your nation inglest countries in the continuous countries and the decimal production of the continuous countries and the continuous countries are continuous continu Flurac is indicated alone or in combination for the palliative treatment of malignant tumours, particularly of the breast, colon or rectum; and in the present of malignant tumours, particularly of the breast, colon or rectum; and in the present of the breast colon or rectum; and in the present of the breast colon or rectum; and in the present of the breast colon or rectum; and in the present of the breast colon or rectum; and in the present of the breast colon or rectum; and in the present of the breast colon or rectum; and in the present of the breast colon or rectum; and in the present of the breast colon or rectum; and in the present of the breast colon or rectum; and in the present of the breast colon or rectum; and in the present of the breast colon or rectum; and in the present of the breast colon or rectum; and in the present of the breast colon or rectum; and the present of the breast colon or rectum; and the present of the breast colon or rectum; and the present of the breast colon or rectum; and the present of the breast colon or rectum; and the present of the breast colon or rectum; and the present of the breast colon or rectum; and the present of the breast colon or rectum; and the present of the breast colon or rectum. the treatment of gastric, primary hepatic, pancreatic, uterine (cervical particularly), ovarian and bladder carcinomas, and the state of the state o Flurac should only be used when other proven measures have failed or are considered impractical.

Contraindications:

is tampines, need eyent virgus semileau lans cuidh as muifes artuna ambiil i ann abhrail arthru. Th Flurac is contra-indicated in patients with bone marrow depression after radiotherapy or treatment with other antineoplastic agents.

Warning & Precautions:

It is recommended that Flurac be given only by or under strict supervision of a qualified physician who is well acquainted with the use of potent and a qualified physician who is well acquainted with the use of potent metabolites. Because of the possibility of severe toxic reactions, all patients should be hospitalized, at least during the initial course of therapy, Flurac should not be re-administered after a documented cardiovascular reaction (arrhythmia, angina, ST segment changes) as there is a risk of personal control of the cont

Rarely, severe and unexpected toxic reactions (including stomatitis, diarrhea, neutropenia and neurotoxicity) have been reported in association

with Flurac. These reactions have been attributed to deficiency of dipyrimidine dehydrogenase activity, which appears to cause prolonged Dianaki in aya **8**10

Any form of therapy that adds to the stress of the patient, interferes with nutritional uptake or depress bone marrow function, will increase the

toxicity of Flurace, tonco proceed needs as not the control of the second as the control of the the 9th and 14th day of the first course, but occasionally being delayed for as long as 20 days. The count usually returns to normal by the 30th day. Daily monitoring of platelet and WBC counts are recommended and treatment should be stopped if platelets fall below 100,000 per mm3 or the WBC count falls below 3500 per mm3. If the WBC count falls below 2000 per mm3, it is recommended that the patients be placed in protective isolation in the hospital and given the appropriate preventative treatment for systemic infection.

Treatment should also be discontinued at the first sign of oral ulceration or if there is evidence of gastrointestinal side effects such as stomatitis, diarrhea, bleeding from the gastrointestinal tract, oesophagopharyngitis or intractable vomiting.

The ratio between effective and toxic dose is small and therapeutic response is unlikely without some degree of toxicity. Care must be taken therefore, in the selection of patients and adjustment of dosage.

Flurac should be used with caution in patients with reduced renal or liver function, jaundice or heart disease.

Flurac should be used with caution in elderly patients. An age of 70 years or older and the female gender are reported independent risk factors for severe toxicity from Flurac based chemotherapy.

Close monitoring for multiple organ toxicities and vigorous supportive care of those with toxicity are necessary.

Combination chemo-or radiotherapy may depress bone marrow function and increase the toxicity of Flurac. Extreme caution is necessary when administering fluorouracil to patients who have had high dose pelvic irradiation, or have been previously treated with alkylating agents.

Pregnancy

Category D. Flurac may cause fetal harm when administered to a pregnant woman. There are no adequate and well-controlled studies in Source pregnant women. Flurac administered parenterally has been shown to be teratogenic in mice, rats and hamsters, and embryolethal in monkeys. Flurac is strictly contraindicated in pregnancy.

All softs solved developed because many reduction social to environment in a first or a

Use in lactation

It is not known whether Flurac is excreted in breast milk. To avoid possible harmful effects in the infant, breast-feeding is not advised during and a second Flurac therapy. brittable suice of

Drug Interactions:

Leucovorin calcium may enhance the toxicity of Flurac.

Combination Therapy

Any form of therapy which and to the stress of the patient, interferes with nutrition or depresses bone marrow function will increase the toxicity of Flurac.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Dosage and Administration:

Mode of administration:

Flurac injection is given as Intravenous injection and Intravenous infusion. Flurac injection, requires dilution before administration as infusion.

Flurac Injection may be administered by intravenous infusion or intravenous injection, the dosage being based on the patient's actual weight. Ideal weight is used only if the patient is obese or if there has been a spurious weight gain due to oedema, ascites or other forms of abnormal fluid retention.

The total daily dose of Flurac should not exceed 1 gram. The initial recommended doses should be reduced by one third to a half if any of the following conditions are present:

- (1) poor nutritional state
- (2) after major surgery (within previous 30 days)
- (3) inadequate bone marrow function (WBC count less than 5,000 per mm3; platelet count less than 100,000 per mm3)
- (4) impaired hepatic and/or renal function

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วอยู่สะใจ คืออริจิสโลส์ อัสโลส์ Intravenous infusion

15 milligrams/kg body weight diluted in 300 to 500 mL of 5% glucose given over a period of 4 hours. The infusion may be repeated daily until the first gastrointestinal side effects (eg. Stomatitis, diarrhoea) or haematological side effects (eg. Leucopenia, thrombocytopenia) appear.

Treatment must be discontinued until the side effects have receded (until the WBC count has risen to 3,000 to 4,000 per mm3 and the platelet count to 80,000 to 100,000 per mm³). The patient may then be placed on a maintenance therapy program.

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Intravenous injection

12 milligrams/kg body weight daily for 3 consecutive days.

Providing there are no signs of toxic effects, the patient may then be given 6 milligrams/kg intravenously on the 5th, 7th and 9th days. If after the 9th day there is still no sign of toxicity, the patient may be placed on maintenance therapy. In all instances toxic side effects must 100 (100) resolve before maintenance therapy is started.

Maintenance theraby regarded in the following and the control of t

5 to 10 milligrams/kg body weight by intravenous injection once a week. Toxic symptoms seldom occur during maintenance therapy. If, however, they do appear, therapy must be discontinued until the symptoms resolve.

Other methods of administration

Flurac may be used in combination with other cytotoxic agents or with radiotherapy. In such cases doses should be correspondingly reduced the content of the Flurac Injection may also be administrated as a 24 hour intra-arterial continuous drip infusion (5 to 7.5 milligrams/kg bodyweight daily).

Adverse Effects:

Stomatitis and esophagopharyngitis (which may lead to sloughing and ulceration), diarrhea, anorexia, nausea and emesis are commonly seen and emesis are commonly

Leukopenia usually follows every course of adequate therapy with Flurac. The lowest white blood cell counts are commonly observed between the 9th and 14th days after the first course of treatment, although uncommonly the maximal depression may be delayed for as long as 20 days. By the 30th day the count has usually returned to the normal range; will be all execute very limited from the count has usually returned to the normal range; will be all execute very limited from the country and the countr

Alopecia and dermatitis may be seen in a substantial number of cases. The dermatitis most often seen is a pruritic, maculopapular rash usually appearing on the extremitles and less frequently on the trunk. It is generally reversible and usually responsive to symptomatic treatment of the AVA to expose the content of the AVA to expose the co

Hematologic: pancytopenia, thrombocytopenia, agranulocytosis, anemia.

Cardiovascular. myocardial ischemia, angina.

Gastrointestinal gastrointestinal ulceration and bleeding. The second se

Neurologic: acute cerebellar syndrome (which may persist following discontinuance of treatment), nystagmus, headache.

Dermatologic: dry skin, fissuring, photosensitivity, as manifested by erythema or increased pigmentation of the skin, vein pigmentation; palmar plantar erythrodysesthesia syndrome, as manifested by tingling of the hands and feet following by pain, erythema, and swelling.

Ophthalmic Lacrimal duct stenosis; visual changes, lacrimation; photophobia.**

Psychiatric: disorientation, confusion, euphoria.

Miscellaneous: thrombophlebitis, epistaxis, nail changes (including loss of nails). er Salam (film) der etter om <mark>amal bruc</mark>e (klara alam, carefylmska)

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The possibility of overdosage with Flurac is unlikely in view of the mode of administration. Nevertheless, the anticipated manifestations would be nausea, vomiting, diarrhea, gastrointestinal ulceration and bleeding, bone marrow depression (including thrombocytopenia, leukopenia and and and all the state of the state agranulocytosis). No specific antidotal therapy-exists: Patients who have been exposed to an overdose of Fluorouracil should be monitored hematologically for at least four weeks. Should abnormalities appear, appropriate therapy should be utilized. nomen in a superior for the comment of the second of the s laside gad bein

Effects on Ability to Drive and Use Machine:

No studies on the effects on the ability to drive and use machinery have been performed.

Fluorouracil may induce side effects such as nausea and vomiting. It can also produce adverse event on nervous system and visual changes and vomiting. which could interfere driving or the usage of heavy machinery.

ell i suam i ubi mem allegum forgeli like i cup suo nelekne que mintension monti pum cui a cul oci. Rumet cem em únaciolá Flurac is incompatible with carboplatin, cisplatin, cytarabine, diazepam, doxorubicin, other anthracyclines and possibly methotrexate. Formulated solutions are alkaline and it is recommended that admixture with acidic drugs or preparations should be avoided.

Instructions for Use: 100 Percent of the Common Com Chemical and physical in-use stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or Sodium Chloride 0.9% Injection B.P. of The angle of the stability has been demonstrated for 48 hours at 25°C with Glucose 5% or 50°C with Water for Injections B.P at concentration 0.98 mg/ml of fluorouracil. From a microbiological point of view, the product should be used immediately. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless dilution has taken place in controlled ក្រាសាស្រាល់ស្រាល់សាស្រាល់ (Norwall 🖔 Tellerate and search these thinks a beautiful a part of and validated asentic conditions. មានមាទី នាំទោះ ខាន់ ភាគ្នាក្រក់ប្រើប្រែស្លាន The product should be discarded if it appears brown of dark yellow in solutional actual control of grant and the product should be discarded if it appears brown of dark yellow in solutional actual control of grant and the product should be discarded if it appears brown of dark yellow in solutional actual control of grant and the product should be discarded if it appears brown of dark yellow in solutional actual control of grant and the product should be discarded in The remainder of solutions should be discarded after use: do not make up into multidose preparations. See the Delicities selected to the selected of the selec calle evidence of the first and the second of the property actions of the second of th Presentation: For intravenous use. Flurac injection is available as follows: 1997 April 199 tig mineral bis court from the good for it wanted inserts describing on puggids at the court field in realizati 5 ml containing 250 mg of Fluorouracil (50 mg/ml) 10 ml containing 500 mg of Fluorouracii (50 mg/mi) 54 of 60 de service de ser dan daya sa basar da mina ang spesiaso a maintain a sa kara sa da sago. 20 ml vial containing 1 gm of Fluorouracil (50 mg/ml) 100 ml vial containing 5 gm of Fluorouracil (50 mg/ml) and and the land the land the land the section has been proceed that the land the l รอยอรังเทียกร้อง รายครั้งกรัฐสาที่อาหาย ของ ตา e i i de grapita de a segunda en altaga, gada na Ancia de a a cinique sa contra de a contra de contra de contra Shelf life Consider the Page Committee of the endoctrophetally Two years from the date of manufacturing. The property of the control of the cont g to the liver of the second control of the mental and operating the event of the sequencial of the second of the Store below 25°C. 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