There are no adequate and well-controlled studies with FUDR in pregnant women. While there is no evidence of teratogenicity in humans due to FUDR, it should be kept in mind that other drugs which inhibit DNA synthesis (e.g., methotrexate and aminopterin) have been reported to be teratogenic in humans. FUDR should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects:
Floxuridine has not been studied in animals for its effects on peri- and postnatal development. However, compounds which inhibit DNA, RNA and protein synthesis might be expected to have adverse effects on peri- and postnatal development.

Negative Mutations:
It is not known whether FUDR is excreted in human milk. Because FUDR inhibits DNA and RNA synthesis, mothers should not nurse while receiving this drug. Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS
Adverse reactions to the arterial infusion of FUDR are generally related to the procedural complications of regional arterial infusion.

The more common adverse reactions to the drug are nausea, vomiting, diarrhea, anorexia, stomatitis and localized erythema. The more common laboratory abnormalities are anemia, leukopenia, thrombocytopenia and elevations of alkaline phosphatase, serum transaminase, serum bilirubin and lacto-dehydrogenase.

Other adverse reactions are:
Gastrointestinal: duodenal ulcer, duodenitis, gastritis, bleeding, gastronecrosis, glossitis, pharyngitis, anorexia, cramps, abdominal pain, possible intra- and intrabiliary biliary scleroses, as well as analgesic cholelithias.
Dermatologic: alopecia, dermatitis, non-specific skin toxic rash.
Cardiovascular: myocardial ischemia.
Miscellaneous Clinical Reactions: fever, lethargy, malaise, weakness.

Laboratory Abnormalities: BSR, prothrombin, total proteins, sedimentation rate and thromboplastin.

Procedural Complications of Regional Arterial Infusion: arterial aneurysm, arterial thrombosis; embolism; fibromyositis; thromboembolism; hepatic necrosis; abscesses; infection at catheter site; bleeding at catheter site; catheter blockage.

The following adverse reactions have not been reported with FUDR but have been noted following the administration of 5-fluorouracil, and since the possibility of these occurring following FUDR therapy is remote because of its regional administration, one should be alert for these reactions following the administration of FUDR because of the pharmacological similarity of these two drugs: pancreatitis, agranulocytosis, myelosuppression, anemia, anaphylaxis, generalized allergic reactions, acute cerebellar syndrome, syncope, headach, deep skin, friability, photosensitivity, gastric mucosal ulceration, increased skin pigmentation, lacrimal duct stenosis, visual changes, lacrimation, photophobia, disorientation, confusion, euphoria, epistaxis and nail changes, including loss of nails.

OVERDOSAGE
The possibility of overdose with FUDR 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 agranulocytosis). No specific antidotal therapy is available; patients who have been exposed to an overdose of FUDR should be monitored hematologically for at least 4 weeks. Should abnormalities appear, appropriate therapy should be utilized.

The acute intravenous toxicity of floxuridine is as follows:

Species  $LD_{50}$ (mg/kg ± S.E.)
---
Mouse  880 ± 51
Rat  670 ± 73
Rabbit  94 ± 16
Dog  157 ± 46

DOSAGE AND ADMINISTRATION

Each vial must be reconstituted with 5 mL of sterile Water for Injection to yield a solution containing approximately 100 mg of floxuridine/mL. The calculated daily dose(s) of the drug is then diluted with 5% dextrose or 0.9% sodium chloride solution to volumes of 100 to 250 mL. The drug is administered over 45 to 60 minutes at a rate not exceeding 5 mL/minute.

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