Precautions

General: Appropriate consideration of the cardiac status of the patient must be made before administration of fluorescein sodium injection. Caution is to be exercised in patients with a history of hypersensitivity, allergies, or asthma. In case of emergency, a tray including such items as 1:1,000 epinephrine for intravenous or intramuscular use; an antihistamine, soluble steroid, aminophylline for IV use; and oxygen should always be available for possible reaction to fluorescein sodium injection. This solution is supplied sterile in the unopened container and is intended for one-time use. Discard any unused solution. Carcinogenesis, Mutagenesis, Impairment of Fertility: No long-term animal studies have been performed to assess the carcinogenesis, mutagenesis or impairment of fertility due to fluorescein sodium.

Pregnancy:TeratogenicEffects-PregnancyCategoryC.Animal reproductionstudieshavenotbeen conductedwithfluorescein sodium.It isalsonotknownwhetherfluoresceinsodiumcan causefetal harm whenadministeredtoa pregnantwomanor canaffectreproductioncapacity.Fluoresceinsodium should begiven toapregnantwomanonlyif clearlyneeded.NursingMothers:Itisnot knownwhether thisdrug isexcretedinhumanmilk.Becausemany drugsareexcretedinhumanmilk,cautionshouldbe exercised when fluoresceinsodiuminjectionisadministeredtoa nursingwoman.

Pediatric Use: Safety and effectiveness in children have not been established.

Adversereactions

The following adverse reactions have been reported after use of fluorescein sodium injection: cardiac arrest, acute myocardial infarction, basilar artery ischemia, thrombophlebitis at the injection site, severe shock, and other signs and symptoms of hypersensitivity, convulsions, syncope, pyrexia, transient dyspnea, angioneurotic edema, moderate to marked nausea and headache, gastrointestinal distress, slight dizziness, urticaria and pruritus. Rare cases of death have been reported.

Themostcommonreactionisnausea,reportedtooccurin1-15%ofallpatients.Extravasationofthe solutionattheinjectionsitecausesintensepainatthesiteanddull,achingpainintheinjectionarm. Thesesymptomsareselflimiting.Thesereactionsgenerallyarenotedsoonafterinjectionandmay occurirrespectiveofpreviousexposuretothedye.Localizedeczematousdermatitisisreportedrarely tohaveoccurredonedayafterinjection.

Dosage& Administration

Inject contents of ampoule rapidly into the antecubital vein. In 9 to 14 seconds luminescence appears in the retinal and choroidal vessels which can be observed by standard viewing equipment. If potential allergy is suspected, an intradermal skin test may be performed prior to intravenous administration. ie 0.05 ml. Injected intradermally to be evaluated 30 to 60 minutes following injection. An EMERGENCY TRAY including such items as 0.1% epinephrine for intravenous or intramuscular use, an antihistamine injection and oxygen should always be available. For children, the dose is calculated on the basis of 35 mg for each 5kg of body weight. Discard any unused portion.

Presentation

Fluresissuppliedinsingleuse3mlampoulesinboxesof10ampoules.Protectfromlight.

Storage

Store at 2ºC & 35ºC.

pharmafabrikon
Unit II, 91-1, Sivagangai Road,
Vilathur, Madurai- 625 020.

Marketedby:

aurolab
No.1, Sivagangai Main Road,
Veerapanjan,
Madurai - 625 020.
INDIA.

TSPMED 08 **Issue No 02** **Date 15/3/11**

112mm

82mm

INSTRUCTIONFORUSELEAFLET
FLURES3ml
(FLUORESCEININJECTION20%w/vUSP)

Description

FlurescontainsFluoresceinsodiumequivalenttoF luorescein20%w/v.Itis aste rileaqueoussolution foruseintravenouslyasadia gnosticaid.Iti ssuppliedasa nunpreservedsingle use aqueoussolution thathasa pHof8.0 9.8.

ClinicalpharmacologyMechanismof Action
Fluorescein sodium responds to electromagnetic radiation and light between the wavelengths of 465-490 nm and fluoresces, i.e., emits light at wavelengths of 520-530 nm. Thus, the hydrocarbon is excited by blue light and emits light that appears yellowish-green. Following intravenous injection of fluorescein sodium in an aqueous solution, the unbound fraction of the fluorescein can be excited with a blue light flash from a fundus camera as it circulates through the ocular vasculature, and the yellowish green fluorescence of the dye is captured by the camera. In the fundus, the fluorescence of the dye demarcates the retinal and/or choroidal vasculature under observation, distinguishing it from adjacent areas/structures.

Pharmacokinetics
Distribution:
Within 7 to 14 seconds after IV administration into antecubital vein, fluorescein usually appears in the central artery of the eye. Within a few minutes of IV administration of fluorescein sodium, a yellowish discoloration of the skin occurs, which begins to fade after 6 to 12 hours of dosing. Various estimates of volume of distribution indicate that fluorescein distributes well into interstitial space (0.5 L/kg).

Metabolism:
Fluorescein undergoes rapid metabolism to fluorescein monoglucuronide. After IV administration of fluorescein sodium (14 mg/kg) to 7 healthy subjects, approximately 80% of fluorescein in plasma was converted to glucuronide conjugate after a period of 1 hour post dose, indicating relatively rapid conjugation.

Excretion:
Fluorescein and its metabolites are mainly eliminated via renal excretion. After IV administration, the urine remains slightly fluorescent for 24 to 36 hours. A renal clearance of 1.75 mL/min/kg and a hepatic clearance (due to conjugation) of 1.50 mL/min/kg have been estimated. The systemic clearance of fluorescein was essentially complete by 48 to 72 hours after administration of 500 mg fluorescein.

Indication

Fluorescein sodium is indicated for ophthalmic angiography and angioscopy in diagnostic examination of the fundus; in evaluation of the iris vasculature; to differentiate between viable and non-viable tissue; to assess aqueous flow; in differential diagnosis of malignant and non-malignant tumors; and in determination of circulation time and adequacy of the circulation.

Contraindications

Contraindicatedint hosepersonswhohaveshownhypersensitivitytoan ycomponentofthis preparation.

Warnings
Care must be taken to avoid extravasation during injection as the high pH of fluorescein solution can result in severe local tissue damage. The following complications resulting from extravasation of fluorescein have been noted to occur: Sloughing of the skin, superficial phlebitis, subcutaneous granuloma,and toxic neuritis along the median curve in the antecubital area. Complications resulting from extravasation can cause severe pain in the arm for up to several hours. When significant extravasation occurs, the injection should be discontinued and conservative measures to treat damaged tissue and to relieve pain should be implemented. Rare cases of death due to anaphylaxis have been reported (See Precautions)

112mm

82mm