

ISOSULFAN BLUE - isosulfan blue solution
AnazaoHealth Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Isosulfan Blue 1%

DESCRIPTION

Dear Medical Professional,

Per your order we have compounded Isosulfan Blue 1%. The characteristics of this compounded preparation are as follows:

CLINICAL PHARMACOLOGY

Isosulfan Blue has no known pharmacologic action. Following subcutaneous administration, Isosulfan blue 1% is selectively picked up by the lymphatic vessels. Thus, the lymphatic vessels are delineated by a bright blue color making them discernible from surrounding tissue. There is some evidence that 50% of the isosulfan blue, from aqueous solution, is weakly bound to serum protein (albumin). Since interstitial protein is presumed to be carried almost exclusively by lymphatics, and in view of evidence of binding of dyes to proteins, visualization may be due to protein binding phenomenon.

INDICATIONS AND USAGE

Isosulfan Blue 1% Injection delineates the lymphatic vessels following subcutaneous administration. It is an adjunct to lymphography (in primary and secondary lymphedema of the extremities; chyluria, chylous ascites or chylothorax; lymph node involvement by primary or secondary neoplasm; and lymph node response to therapeutic modalities) for visualization to the lymphatic system draining the region of injection

DOSAGE AND ADMINISTRATION

Isosulfan Blue 1% is to be administered subcutaneously, one-half (1/2) ml into three (3) interdigital spaces of each extremity per study. A maximum dose of 3 ml (30 mg) isosulfan blue is injected.

CONTRAINDICATIONS

Hypersensitivity to triphenylmethane or related compounds

PRECAUTIONS

After subcutaneous administration of Isosulfan blue 1%, competent personnel and emergency facilities should be available for at least 30-60 minutes, since severe delayed reactions have been known to occur with similar compounds.

The admixture of Isosulfan blue with local anesthetics (i.e. lidocaine) in the same syringe prior to administration resulted in an immediate precipitation of 4-9% of the drug complex. This technique is not recommended

ADVERSE REACTIONS

Isosulfan blue 1% has demonstrated a 1.5% incidence of adverse reactions. All the reactions were of an allergic type such as localized swelling at the site of administration and mild pruritis of hands, abdomen and neck have been reported within several minutes following administration of the drug.

Storage and Handling

Store at room temperature

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1



ISOSULFAN BLUE

isosulfan blue solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51808-206
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOSULFAN BLUE (UNII: 39N9K8S2A4) (ISOSULFAN BLUE - UNII:39N9K8S2A4)	ISOSULFAN BLUE	10 mg in 1 mL

Product Characteristics

Color	BLUE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51808-206-01	5 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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Unapproved drug other		06/19/2012	
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Labeler - AnazaoHealth Corporation (011038762)

Establishment

Name	Address	ID/FEI	Business Operations
AnazaoHealth Corporation		011038762	MANUFACTURE

Revised: 6/2012

AnazaoHealth Corporation