



physicians who are familiar with an acceptable injection technique.

Patients in Child Class C are more likely to develop esophageal ulceration than those in Classes A and B. Complications of ulceration, necrosis, and delayed esophageal perforation appear to occur more frequently when ETHAMOLIN Injection is injected submucosally. This route is not recommended.

In patients with concomitant cardiorespiratory disease, careful monitoring and minimization of the total dose per session is recommended.

Fatal aspiration pneumonia has occurred in elderly patients undergoing esophageal variceal sclerotherapy with ETHAMOLIN Injection. This adverse event appears to be procedure-related, rather than drug-related; but as aspiration of blood and/or stomach contents is not uncommon in patients with bleeding esophageal varices, special precautions should be taken to prevent its occurrence, especially in elderly and critically-ill subjects.

### **Pregnancy: (Teratogenic Effects: Pregnancy Category C)**

Animal reproduction studies have not been conducted with ETHAMOLIN Injection. It is also not known whether ETHAMOLIN Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ETHAMOLIN Injection should be given to a pregnant woman only if clearly needed.

### **Nursing Mothers**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when ETHAMOLIN Injection is administered to a nursing woman.

### **Pediatric Use**

Safety and effectiveness in pediatric patients have not been established.

### **ADVERSE REACTIONS**

The reported frequency of complications/adverse events per injection session was 13%. The most common complications were pleural effusion/infiltration (2.1%), esophageal ulcer (2.1%), pyrexia (1.8%), retrosternal pain (1.6%), esophageal stricture (1.3%), and pneumonia (1.2%).

Other adverse local esophageal reactions have also been reported at rates of 0.1 to 0.4%, including esophagitis, tearing of the esophagus, sloughing of the mucosa overlying the injected varix, ulceration, stricture, necrosis, periesophageal abscess and perforation (see PRECAUTIONS). These complications appear to be dependent upon the dose and the patient's clinical state.

Bacteremia has been observed in patients following injection of esophageal varices with ETHAMOLIN. Pyrexia and retrosternal pain are not infrequently observed during the post-injection period. Fatal aspiration pneumonia has occurred in patients with esophageal varices who underwent ETHAMOLIN Injection Sclerotherapy (see PRECAUTIONS). Anaphylactic shock and acute renal failure with spontaneous

recovery have occurred (see PRECAUTIONS). A case of disseminated intravascular coagulation has been reported.

Spinal cord paralysis due to occlusion of the anterior spinal artery has been reported in one child eight hours after ETHAMOLIN sclerotherapy.

### **DRUG ABUSE AND DEPENDENCE**

There is no potential for drug abuse or drug dependence.

### **OVERDOSAGE**

Overdosage of ETHAMOLIN Injection can result in severe intramural necrosis of the esophagus. Complications resulting from such overdosage have resulted in death.

### **DOSAGE AND ADMINISTRATION**

Local ETHAMOLIN Injection sclerotherapy of esophageal varices should be performed by physicians who are familiar with an acceptable technique. The usual intravenous dose is 1.5 to 5.0 mL per varix. The maximum dose per treatment session should not exceed 20 mL. Patients with significant liver dysfunction (Child Class C) or concomitant cardiopulmonary disease should usually receive less than the recommended maximum dose. Submucosal injections are not recommended as they reportedly are more likely to result in ulceration at the site of injection.

To obliterate the varix, injections may be made at the time of the acute bleeding episode and then after one week, six weeks, three months, and six months, as indicated.

Note: Parenteral drug products should be inspected visually for particulate matter and discoloration before administration whenever solution and container permit.

### **HOW SUPPLIED**

NDC	SIZE
67871-4790-6	2 mL ampule

ETHAMOLIN® (Ethanolamine Oleate) Injection, 5% is available in 2 mL, sterile, single-use glass ampules supplied as boxes of 10 ampules.

### **Storage**

Store at controlled room temperature, 15°– 30°C (59°– 86°F). Protect from light.

### **Distributed by: QOL Medical, LLC**

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