

Celltech Pharmaceuticals Ltd. Data Sheet
Information for the medical and Pharmaceutical Profession

ETHANOLAMINE OLEATE INJECTION BP

Presentation

Ampoules of 5 ml containing Ethanolamine BP 0.91% w/v and Oleic Acid BP 4.23% w/v Water for Injection, presented as a clear, pale yellow solution.

Uses

Ethanolamine Oleate acts as a sclerosant, irritating the intimal endothelium of the injected vein to form a thrombus. The latter occludes the vein and fibrous tissue develops resulting in permanent obliteration of the vein.

The injection is used as a sclerosing agent in the treatment of small, uncomplicated varicose veins in the lower extremities.

Dosage and administration

The product is used only as sclerosant and is injected into the varicose vein. Submucosal injections are not recommended as they are reportedly more likely to result in ulceration at the site of injection.

The affected vein or veins are marked after identification by application of a tourniquet and 0.5 ml to 1.5 ml injected into each vein to be treated. The treatment may be repeated if necessary at weekly intervals. The maximum total dose per treatment should not exceed 20 milliliters.

It is normal to strap the whole of the leg containing the varicose veins up to the thigh using an elastic stocking for a period of 6 to 8 weeks and the patient directed to walk at least 3 miles each day. The exercise helps to ensure a successful outcome to the treatment.

Contra – indications, warnings etc.

Contra-indications: Inability to walk, oral contraceptive use, obese legs. Hypersensitivity to Ethanolamine oleate or benzyl alcohol, acute superficial thrombophlebitis and deep vein thrombosis in the region of varicose veins.

Warnings: Care should be taken to ensure that the injection does not leak into perivenous tissue which could cause sloughing.

Precautions: adrenaline injection should be available for use in case the need arises for emergency treatment of an allergic reaction.

Acute renal failure with spontaneous recovery followed injections of 15 to 20 ml in two women.

Severe injection necrosis may result from direct injection of sclerosing agents, especially if excessive volumes are used. At least one fatal case of extensive esophageal necrosis and death has occurred. The drug should be administered by physicians who are familiar with an acceptable injection technique.

Concomitant cardiorespiratory disease: careful monitoring and minimization of the total dose per session is recommended.

Use in Pregnancy: Safety during pregnancy has not been established, and it is recommended that treatment be delayed until after delivery.

Lactation: it is not known whether this drug is excreted in breast milk.

Exercise caution when Ethanolamine is administered to a nursing woman.

Children: Safety and efficacy in children have not been established. In one study, 21 children with esophageal varices were treated with Ethanolamine oleate via an endotracheal tube using 2 to 5 ml injection per varix to a maximum of 20 ml. Variceal obliteration occurred in 18 of the children.

Side Effects: burning, cramping sensation, urticaria. Allergic reactions and anaphylaxis (including one fatal case) have been reported following use of sclerosing agents.

Bacteremia; renal failure with spontaneous recovery (see precautions).

Pharmaceuticals Precautions

Store below 25°C and protect from light.

Contains Benzyl Alcohol BP 2% v/v.

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Legal Category: POM.

Package quantities: Ampoules of 5ml in cartons of 10.

Further Information: The injection has a pH of 8.0 to 9.0.

Product License Number: 116.63.21433

Manufacturer: Celltech Pharmaceuticals Limited, Lancashire, UK.

Importer: Mediline Ltd., P.O.B. 531 Yokneam Ellit 20692