

# ***Centre for Advanced Medicine Ltd***

## **Edetate Disodium USP (EDTA) Solution for Injection**

<b>Bottle size / volume</b>	<b>100ml solution in clear glass bottles</b>
<b>Solution concentration</b>	<b>150mg/ml as edetate disodium (EDTA)</b>
<b>Shelf life</b>	<b>Three years</b>

### **Product registration**

EDTA injectible solution produced by Centre for Advanced Medicine Ltd is registered by the Ministry of Health as a pharmaceutical medicine for intravenous injection (Ministry of Health Registration TT50-3648). The manufacturing facility is located in Auckland, and its operations comply with standards set by the Ministry of Health and the World Health Organisation.

### **Product description.**

Each millilitre of EDTA solution contains 0.15 grams of disodium dihydrogen tetraacetic acid USP (expressed as the anhydrous salt) dissolved in pyrogen-free water for injection. The pH of the solution is adjusted during manufacture to remain in the range 6.5 to 7.5. The solution is contained in a 100ml clear glass bottle, sealed with a medical-grade pure natural rubber septum retained by an aluminium screw cap. The cap is covered with an adherent aluminium IVA foil seal, and the cap and seal are secured to the bottle with heat-shrink plastic.

### **Sterilization**

The EDTA solution is filtered to injectible standards during manufacture, prior to bottling. Following capping, the entire bottle is autoclaved to terminal sterilization standard.

### **Shelf life**

As a result of the stringent manufacturing process, the EDTA solution produced by Centre for Advanced Medicine Ltd has a shelf life of three years from date of manufacture.

### **Air filter unit and needle**

A sterile 0.22 micron air filter unit and a sterile 18 gauge needle are supplied with every bottle of product.

### **Sterile withdrawal of solution**

Before any EDTA solution is withdrawn from the bottle, the sterile needle (provided by the purchaser) is fitted aseptically to the filter unit and inserted through the septum. The needle remains in the septum until all the solution has been used or discarded. This procedure ensures that solution can be withdrawn by syringe and air entering the bottle is sterile, thereby maintaining sterile conditions within the bottle at all times.

**Multiple withdrawals of solution**

The pure natural rubber septum is of a type which re-seals after being punctured by the syringe needle used to withdraw a dose of solution. This feature, together with the provision for sterilization of air entering the bottle, enables multiple withdrawals of solution to be made from the bottle (in those jurisdictions where multiple withdrawals are permitted).

**Payment and Delivery**

Standard packaging	Carton containing 12 bottles
Unit price (cartons)	POA. Please confirm price on ordering.
Freight	Additional (charged at cost)

**Contact information**

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