IE

LiDCO Cardiac Sensor Systems

PATIENT INFORMATION LEAFLET

LITHIUM CHLORIDE 0.15mmol/ml SOLUTION FOR INJECTION

Read all of this leaflet carefully before you have this injection.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, please ask your doctor or nurse.*

What is the Lithium Chloride 0.15mmol/ml Solution for Injection?

The Lithium Chloride 0.15mmol/ml Solution for Injection is used with the LiDCO System. It consists of an ampoule that contains a sterile solution of 63.6mg of lithium chloride in 10ml of water (6.36mg/ml).

Lithium chloride is a natural salt. It is normally present in very small amounts in drinking water and in your body.

Each dose is administered via an intravenous injection that will be given to you by your doctor or nurse.

This product is supplied in cartons of 5 ampoules.

Marketing authorisation holder:
LiDCO Netherlands B.V.
Van Heuven Goedhartlaan 935A
1181LD Amstelveen
The Netherlands

Manufacturer:
Torbay Pharmaceuticals
Torbay and South Devon NHS Foundation Trust
Wilkins Drive
Paignton
TQ4 7FG
United Kingdom

Continued overleaf.....

DATA SHEET
Lithium Chloride 0.15mmol/ml Solution for Injection

Presentation
Glass ampoule containing l0ml of a sterile solution of lithium chloride (0.15mmol/ml) in Water for Injection.

Uses
For use only as an *in-vivo* diagnostic for the measurement of cardiac output used in conjunction with the LiDCO System.

Dosage and Administration
Dose Range - A single dose of 0.075mmol (0.5ml), 0.15mmol (1ml) or 0.3mmol (2ml) Lithium Chloride 0.15 mmol/ml Solution for Injection is required per cardiac output determination. The dose chosen is the smallest that will produce an arterial plasma lithium dilution curve with a peak of between 0.2 and 0.8mM. At least 5 minutes should be allowed before a subsequent lithium dilution cardiac output measurement is made.

Maximum Dose - For all patients a cumulative maximum dose of 3mmol lithium chloride (20ml of solution) is allowed.

Route of Administration - The lithium dose is administered by intravenous injection.

Any unused portion of the Lithium Chloride 0.15mmol/ml Solution for Injection should be discarded.

Contraindications
The use of the Lithium Chloride 0.15mmol/ml Solution for Injection is contraindicated:

- In patients currently under lithium therapy for control of bipolar disorder.
- Patients less than 40kg in weight.
- In the first trimester of pregnancy
- In hypersensitivity to lithium compounds.

Warnings and Precautions

Special warnings and precautions for use
This medicinal product must only be used in conjunction with the LiDCO System

1. Follow the dose recommendations. Inaccuracies occur with blood levels above 0.3 mM and lithium is toxic at blood concentrations above 1.5 mM.

2. All injections of lithium chloride should be recorded in the patient notes.

3. A minimum of 5 minutes should be left between sequential LiDCO System determinations of cardiac output.

4. Waste blood should not be returned to the patient. The waste blood may clot in the bag and/or pick up contaminant material/particles from contact with the Flow Through Cell assembly wick material.

5. Avoid the use of the LiDCO System during the 30 minutes after bolus injections or infusions of muscle relaxant drugs e.g. vecuronium bromide, atracurium besylate and pancuronium bromide. These agents interfere with the performance of the lithium electrode and concurrent use must be avoided.

6. Lithium sensors are affected by other chemicals notably: detergents/surfactants and solvents. Occasional problems have been noted with contaminants present in saline infusion products such as saline bags.

7. The use of the LiDCO System requires the bolus administration of lithium chloride and saline followed by arterial blood sampling. Only medical staff appropriately qualified for the administration of intravenous fluids and peripheral arterial catheter use should use the system. Usual care should be taken to avoid: patient infection, catheter or line disconnection, arterial or venous blood loss and air embolism.

Special warnings and precautions for use *continued*

8. The concurrent use of: electrocautery, electrosurgery, defibrillation and X-ray machinery will cause transient interference with the LiDCO System Monitor trace. Determinations should not be performed during such periods. No such interference is known to occur with infrared irradiation, or equipment generating radiofrequency irradiation.

9. In cases of intracardiac shunt (such as myocardial infarction with interventricular septum rupture), the cardiac output measurement will be distorted when measured by the LiDCO System, as it would by the thermodilution method. An alternative method for cardiac output determination should be considered in such cases.

10. Lithium chloride should not be infused through a line used for the infusion of vasoactive or other potent drugs.

Pregnancy and lactation

Pregnancy

Data are available on the teratogenic effects of normal therapeutic doses of lithium in the first trimester, notably the increased risk of cardiac anomalies, specifically Ebstein's.

Lactation

Although lithium is distributed into the extracellular fluid (ECF), breast-feeding is allowable following the administration of lithium chloride for cardiac output measurement.

Undesirable effects

No undesirable effects related to lithium chloride are expected at the proposed posology.

Overdose

For toxic levels of lithium to be produced, the dose recommendations would have to be exceeded by a factor of more than five. However, the SmPC and the LiDCO System manual contains information on how to recognise lithium toxicity and its treatment.

Haemodialysis for 8-12 hours is recommended when the blood lithium concentration exceeds 3 mM, when the blood concentration is 2-3 mM and the patient's condition is deteriorating, when fluid or electrolyte abnormalities are unresponsive to supportive treatment, when creatinine clearance or urine output decrease substantially, or when the blood lithium concentration is not reduced by at least 20% in 6 hours. Blood lithium concentrations usually rebound within 5-6 hours of haemodialysis because of redistribution, often necessitating repeated courses of haemodialysis. The goal of haemodialysis is to produce a blood lithium concentration of less than 1 mM once 8 hours of haemodialysis is completed. Peritoneal dialysis is less effective at removing lithium and is used only when haemodialysis is not possible.

Pharmaceutical Precautions

Do not store above 25°C.
Store in the original container.

Legal Category

POM

Package Quantities

5 x 10 ml glass ampoules per pack.

Product Authorisation number

PA23039/001/001

Product Authorisation holder & further information from:

LiDCO Netherlands B.V., Van Heuven Goedhartlaan 935A, 1181LD Amstelveen, The Netherlands.
Telephone +31 20 5646 160

Date of Preparation: 14.07.2023

WHAT IS IT USED FOR?

The lithium chloride injection 0.15mmol/ml is for diagnostic use with the LiDCO System. This equipment lets your doctor measure your cardiac output - the amount of blood pumped by your heart each minute.

A small dose is injected into a vein and mixes with the blood in your heart. Your heart pumps this blood, with a trace of lithium chloride, out into your arteries. A small sample of blood is withdrawn from an artery through a small tube that has already been inserted for other reasons (blood pressure measurement, blood sampling, etc.).

This sample passes through the LiDCO sensor that measures the amount of lithium present in your blood, and the LiDCO computer then works out your cardiac output.

The blood sample is then discarded.

WHY DO I NEED THIS INVESTIGATION?

There are many treatments that can be used to improve the performance of the heart and circulation. Normally, blood pressures and the electrical activity of the heart are monitored, but there are occasions when treatment can be better regulated by knowing how much blood the heart is pumping. The LiDCO System is a simple and safe way of doing this.

WHO SHOULD NOT BE GIVEN THE LITHIUM CHLORIDE INJECTION?

Patients on lithium therapy already have a high level of lithium in their blood and are not suitable for investigation with the LiDCO System.

Patients who are receiving muscle-relaxing drugs are not suitable for investigation with the LiDCO System.

The Lithium Chloride 0.15mmol/ml Solution for Injection is not suitable for patients weighing less than 40kg.

The Lithium Chloride 0.15mmol/ml Solution for Injection should not be used during the first 3 months of pregnancy. Breast-feeding is allowable following the administration of lithium chloride for cardiac output measurement.

Your doctor will decide if the LiDCO System is appropriate for measuring your cardiac output. If it isn't, then there are other ways of estimating cardiac output that can be used.

DOSAGE

Usual dose: 0.5 - 2.0ml of solution

Maximum single dose: 2.0ml of solution

Maximum cumulative dose: 20ml of solution

Each dose is administered via an intravenous injection that will be given to you by your doctor or nurse.

ARE THERE ANY SIDE EFFECTS?

The dose of lithium chloride used for measurement of cardiac output is very small and produces no known side effects.

STORAGE

Store out of the reach and sight of children.

Do not use after the expiry date shown on the bottom of the carton and on the ampoule label.

Do not store above 25°C.

Store in the original container.

Leaflet last revised: 14.July.2023

Ref. CM 40-353-116/8