

נובמבר 2021

רופא/ה, רוקח/ת, נכבד/ה,

Phoxilium 1.2 mmol/l Phosphate הנדון:**מרכיבים פעילים:**

Disodium Phosphate Dihydrate
Potassium Chloride
Sodium Chloride
Magnesium Chloride Hexahydrate
Calcium Chloride Dihydrate
Sodium Hydrogen Carbonate

צורת מינון:

Solution for heamodialysis/haemofiltration

התוויות מאושרות:

Phoxilium is used for CRRT (continuous renal replacement therapy) in critically ill patients with ARF (acute renal failure) when pH and kalaemia have been restored to normal and when the patients need phosphate supplementation for loss of phosphate in the ultrafiltrate or to the dialysate during CRRT.

Phoxilium may also be used in cases of drug poisoning or intoxications when the poisons are dialysable or pass through the membrane.

Phoxilium is indicated for use in patients with normal kalaemia and normal or hypophosphataemia.

חברת בקסטר אספקת שירותי בריאות בע"מ מבקשת להודיעכם על עדכונים בעלון לרופא של התכשיר הנדון.
העלון לרופא עודכן בתאריך נובמבר 2021. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באמצעות קו תחתית):

4.4 Special warnings and precautions for use

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Warnings:

Phoxilium should not be used in patients with hyperkalemia (see section 4.3). The serum potassium concentration must be monitored before and during haemofiltration and/or haemodialysis.

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If hyperkalaemia develops when Phoxilium is used as a dialysate, administration of a potassium-free dialysate may be necessary to increase the rate of potassium removal.

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Because Phoxilium contains no glucose, administration may lead to hypoglycaemia. Blood glucose levels should be monitored regularly in diabetic

patients (including careful consideration of patients receiving insulin or other glucose lowering medications), but also considered in non-diabetic patients, e.g. risk for silent hypoglycemia during the procedure. If hypoglycaemia develops, use of a glucose-containing solution should be considered. Other corrective measures may be necessary to maintain desired glycaemic control.

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6.6 Special precautions for disposal and other handling

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Remove any fluid from the injection port, hold the bag upside down, insert the drug through the injection port and mix thoroughly. The introduction and mixing of additives must always be performed prior to connecting the solution bag to the extracorporeal circuit. **The solution must be administered immediately.**

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העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בברכה,
אנסטסיה דזיגר,ב,
מחלקת רישום ורגולציה,
בקסטר אספקט שירותי בריאות בע"מ.