

דצמבר 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 דצמבר 2021. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באמצעות קו תחתית):

4.2 Posology and method of administration**Posology:**

The volume and rate at which Phoxilium is administered depends on the blood concentration of phosphate and other electrolytes, acid–base balance, fluid balance and overall clinical condition of the patient. The volume of replacement solution and/or dialysate to be administered will also depend on the desired intensity (dose) of the treatment. Administration (dose, infusion rate and cumulative volume) of Phoxilium should only be established by a physician experienced in critical care medicine and CRRT (Continuous Renal Replacement Therapy).

The range of flow rates for the replacement solution in haemofiltration and haemodiafiltration are:

Adult: 500 - 3000 ml/hour or 20-35 ml/kg/hr

The range of flow rates for the dialysate in continuous haemodialysis and continuous haemodiafiltration are:

Adult: 500 - 2500 ml/hour or 20-35 ml/kg/hr

Commonly used combined total flow rates for CRRT (dialysate and replacement solutions) in adults are approximately 2000 to 2500 ml/h which correspond to a daily fluid volume of approximately 48 to 60 l.

Paediatric population:

In children from neonates to adolescents to 18 years, the range of flow rates used as substitution solution in haemofiltration and haemodiafiltration and as dialysis solution (dialysate) in continuous haemodialysis and continuous haemodiafiltration are 1000 to 4000 ml/h/1.73 m².

For adolescents (12-18 years), the adult dose recommendation should be used when the paediatric dose is calculated to exceed the maximum adult dose.

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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.