Phoslyra is a phosphate binder.

**What is Phoslyra?**

Phoslyra helps control high levels of phosphate in your blood by binding phosphate in your digestive system. (See "How does Phoslyra work?" below.)

Phosphate binders like Phoslyra are often used to treat high levels of phosphate in the blood of people with kidney failure who are also on dialysis. This is because your kidneys may not work properly and cannot lower your phosphate levels as they should.

Phosphate is a mineral that can be harmful to your body. Too much phosphate in the blood can lead to a condition called hyperphosphatemia. Once high phosphate levels are present, it is important to treat this condition by lowering your phosphate levels.

**How does Phoslyra work?**

Phosphate binders, like Phoslyra, work by binding phosphate in your digestive system so your body cannot absorb it into your blood. Phosphate binders are usually taken with food to help your body absorb the phosphate from the food you eat.

Phosphate binders work as substitutes for dietary phosphate. When you eat foods that are high in phosphate, such as fish, legumes, and nuts, your body absorbs this phosphate into your blood. Phosphate binders prevent your body from absorbing this phosphate by binding to it and keeping it from entering your blood.

**What should I tell my healthcare professional?**

Tell your doctor if you are pregnant or planning to become pregnant, or if you are breastfeeding or planning to breastfeed. Your doctor will weigh the risks and benefits of using Phoslyra during pregnancy or breastfeeding.

Tell your doctor about all of your medical conditions and all of the medicines you take, including prescription and non-prescription medicines (for example, dietary supplements, vitamins and herbal remedies). Your doctor may adjust the dose of certain medicines to make sure they are right for you.

When taking Phoslyra:

- Follow the dosage guidelines on the package label or as directed by your healthcare professional. Be sure to talk to your doctor or pharmacist if you are not sure how much to take.
- Phoslyra is generally started at a low dose and slowly increased by your physician. You should also use the dosing cup provided when taking Phoslyra.
- Do not take Phoslyra with an antacid.
- If you forget to take Phoslyra, it is okay to skip the missed dose. Take the next dose at your regular time. Do not take extra medicine to make up for the missed dose.
- You can take Phoslyra with or without food, but some patients may find that it helps to take it with food.
- Do not take Phoslyra with any other medicines that contain maltitol, a sugar substitute, because it acts in the stomach and intestine.
- Do not take Phoslyra with or near dialysis.
- Do not take Phoslyra with any calcium-based medicines, including antacids.
- Do not take Phoslyra with or near dialysis.
- Do not use Phoslyra with any calcium-based medicines, including antacids.
- Do not take other calcium-based medicines, including antacids.

**What can happen if I take too much Phoslyra?**

Phosphate binders like Phoslyra do not act in the digestive system of people who have had a transplant. Too much Phoslyra can cause hypercalcemia, which is a condition that can result in high levels of calcium in your blood.

**How can I help Phoslyra be most effective?**

- Follow your diet. While taking Phoslyra, you should work with your healthcare professional to follow a diet that contains low levels of phosphate.
- Take Phoslyra consistently as directed by your healthcare professional. You should also use the dosing cup provided when taking Phoslyra.
- Use the dosing cup provided. It is important to take Phoslyra with food. If you are having difficulty taking Phoslyra, talk to your doctor or pharmacist.
- Do not stop taking Phoslyra without talking to your doctor.
- See the "Additional Resources" section at the end of this brochure for websites that you can use to read more about kidney disease.

**Additional Resources**

- www.kidney.org
- Phone: 1-800-638-8299
- Fax: 1-212-689-9261 or 1-212-889-2210
- 30 East 33rd St
- Medical information and patient support.

- www.ars.usda.gov/nutrientdata
- USDA Nutrient Database
- Provides information on nutrition.

- www.niddk.nih.gov
- NIH Building 31 Room 9A06
- Bethesda, MD 20892-2560
- MSC 2560 Office of Communications and research.
- Conducts and supports basic and clinical research.
- www.nephron.com
- The Nephron Information Center
- A dialysis clinic search engine to help patients find the right clinic.

- www.lifeoptions.org
- Educational resources for dialysis patients.

- Fresenius Medical Care North America
- Waltham, MA 02451
- 101543-01 Rev. A 07/2011
- © 2011 Fresenius Medical Care NA. Printed in USA
In clinical studies, calcium acetate has been generally well tolerated. The most common adverse reactions were nausea, vomiting, or diarrhea. Hypercalcemia (>11 mg/dL) was reported in 16% of patients in a 3-month study of a solid dose formulation of calcium acetate; however, the long-term effect of Phoslyra on the progression of vascular or soft tissue calcification has not been determined.

**ADVERSE REACTIONS**

- Hypercalcemia. (4)
- Oral solution: 667 mg calcium acetate per 5 mL. (3)
- May cause diarrhea with nutritional supplements that contain maltitol (5.2)
- Hypercalcemia may aggravate digitalis toxicity.
- In a study of 15 healthy subjects, a co-administered single dose of 4 calcium acetate tablets (approximately 2.7 g) decreased the serum phosphorus in patients with end stage renal disease. (1)

**Pharmacodynamic**

- The data presented in Table 2 demonstrate the efficacy of calcium acetate in the treatment of hyperphosphatemia in end-stage renal disease patients. (1)
- The true magnitude of effect is uncertain.
- No carcinogenicity, mutagenicity, or fertility studies have been conducted with calcium acetate. (4)

**Pharmacokinetic**

- Management of elevated serum phosphorus levels usually includes all of the following: reduction in dietary intake of phosphate, removal of excess oral phosphorus, and discontinuation of Phoslyra. (5.1)
- Avoid the concurrent use of calcium supplements, including calcium-based nonprescription antacids, with Phoslyra.
- Serum calcium increased 9% during the study mostly in the first month of the study. Serum calcium increased 9% during the study mostly in the first month of the study.
- The shelf life is 24 months.

**INDICATIONS AND USAGE**

- Calcium acetate oral solution was studied in a randomized, controlled, 3-arm, open label, cross-over, single-dose study comparing the effects of calcium acetate solution with Phoslyra, commercial calcium acetate gelcaps, and placebo. (3)
- Thirty-five patients completed 3 weeks of calcium acetate gelcaps and 2 weeks of Phoslyra. Ninety-one patients completed at least 6 weeks of the study. (3)
- It is not known whether calcium acetate oral solution is present in the breast milk. (5.2)

**DOSAGE FORMS AND STRENGTHS**

- Oral Solution: 667 mg calcium acetate per 5 mL. (2)
- Hypercalcemia. (4)
- Oral solution: 667 mg calcium acetate per 5 mL. (3)

**CONTRAINDICATIONS**

- Avoid the concurrent use of calcium supplements, including calcium-based nonprescription antacids, with Phoslyra.

**WARNINGS AND PRECAUTIONS**

- Hypercalcemia may aggravate digitalis toxicity.
- In a study of 15 healthy subjects, a co-administered single dose of 4 calcium acetate tablets (approximately 2.7 g) decreased the serum phosphorus in patients with end stage renal disease. (1)

**ADVERSE REACTIONS**

- Hypercalcemia. (4)
- Calcium acetate Placebo

**Table 1: Adverse Reactions in Patients with End-Stage Renal Disease Undergoing Hemodialysis**

<table>
<thead>
<tr>
<th>n (%)</th>
<th>n (%)</th>
<th>n (%)</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 (3.6)</td>
<td>6 (6.1)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
</tbody>
</table>

**OVERDOSAGE**

- The data presented in Table 2 demonstrate the efficacy of calcium acetate in the treatment of hyperphosphatemia in end-stage renal disease patients. (1)
- The true magnitude of effect is uncertain.