

August 29, 2008



## IMPORTANT DRUG WARNING

Dear Healthcare Provider:

Mallinckrodt Inc. would like to inform you of important new safety information in the prescribing information for Phosphocol® P 32 (Chromic Phosphate P 32 Suspension). Phosphocol® P 32 is approved for the intracavitary instillation for the treatment of peritoneal or pleural effusions caused by metastatic disease.

Acute lymphocytic leukemia developed in two children with hemophilia within one year after intra-articular injections of Phosphocol® P 32. Phosphocol® P 32 is not approved by FDA for intra-articular injection.

As a result, the Phosphocol® P 32 package insert contains:

- An additional **WARNINGS** statement:

### **Leukemia**

Phosphocol P32 may increase the risk for leukemia in certain situations. Two children (ages 9 and 14) with hemophilia developed acute lymphocytic leukemia approximately 10 months after intra-articular injections of Phosphocol P32 (0.6 and 1.5 mCi total dose). Phosphocol P32 is not indicated in the intra-articular treatment of hemarthroses.

- An additional **ADVERSE REACTIONS** statement:

### **Post-marketing Experience**

The following adverse reactions associated with the use of Phosphocol P32 have been identified during post approval use:

Leukemia in children (see WARNINGS)

Radiation injury (necrosis and fibrosis) to the small bowel, cecum, and bladder following administration of P32 into the peritoneal cavity.

Please refer to the enclosed PI for the current full Prescribing Information for Phosphocol® P 32.

For any questions, to request more information, or to report serious adverse events suspected to be associated with the use of Phosphocol® P 32, call 1-800-778-7898. Alternatively, adverse event information may be reported directly to the Food and Drug Administration's MedWatch program by phone (1-800-FDA-1088); online (<http://www.accessdata.fda.gov/scripts/medwatch>) or by downloading Form 3500 at <http://www.fda.gov/medwatch/getforms.htm> and sending it to Medwatch by fax (1-800-FDA-0178) or by mail (5600 Fishers Lane, Rockville, MD 20852-9787).

Sincerely,

A handwritten signature in dark ink, appearing to read "Herbert Neuman", is written over a light blue background.

Herbert Neuman, M.D.  
Chief Medical Officer