

June 2006

**Safety Information Regarding Electrolyte Disorders And Nephrocalcinosis: -
Fleet® Phospho-Soda® Oral Solution**

Dear Healthcare Professional:

CB Fleet wishes to inform you of safety concerns that have arisen after use of Fleet® Phospho-soda® Oral Solution, a sodium phosphates oral solution used as a bowel cleanser prior to colonoscopy, x-ray or colon surgery. The two main issues that have arisen are:

- Electrolyte disorders in the 'at-risk' patient population.
- Nephrocalcinosis

Some electrolyte disorders have resulted in fatalities, and cases of significant renal impairment have occurred, therefore new recommendations have been put in place regarding the use of Fleet Phospho-soda oral solution.

1. Use in the elderly, debilitated and other at-risk populations:

Fleet® Phospho-soda® has been rarely associated with severe and potentially fatal cases of electrolyte disorders, the majority involving elderly patients

Therefore the Summary of Product Characteristics has been amended to include the following boxed warning about use in the elderly and at-risk populations:

Fleet® Phospho-soda® has been rarely associated with severe and potentially fatal cases of electrolyte disorders in elderly patients. **The benefit/risk ratio of Fleet® Phospho-soda® needs to be carefully considered before initiating treatment in this at-risk population.** Special attention should be taken when prescribing Fleet® Phospho-soda® to any patient with regard to known contraindications, and the importance of adequate hydration, and in at-risk populations, the importance of also obtaining baseline and post-treatment electrolyte levels.

The 'at-risk' patient population includes the following:

- The elderly
- Debilitated patients
- Those with an increased risk for underlying renal impairment
- Patients with heart disease, acute myocardial infarction or unstable angina
- An increased risk for electrolyte disturbances
 - dehydration
 - gastric retention
 - colitis
 - inability to take adequate oral fluid
 - hypertension or other conditions in which the patients are taking drug products that may result in dehydration (see below)

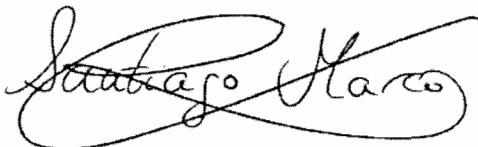
2. Nephrocalcinosis:

Nephrocalcinosis associated with transient renal insufficiency and renal failure has been reported in patients using sodium phosphates for bowel cleansing; the majority of these reports occurred in elderly female patients taking drugs to treat hypertension or other drug products that may result in dehydration such as diuretics, or those taking medications which may decrease glomerular filtration rate, such as angiotensin converting enzyme inhibitors (ACE-Is) angiotensin receptor blockers (ARBs) or non-steroidal anti-inflammatory drugs (NSAIDs). Care should be taken to prescribe Fleet Phospho-soda per recommendations with a particular attention to known contraindications and adequate hydration.

Healthcare Professionals are advised to note and become familiar with the revised safety information.

Careful use of any medical product is vital to its effectiveness and to the safety of patients. **Please read the attached Summary of Product Characteristics carefully as doing so is important in deciding when and how the product should be prescribed for bowel cleansing and for the safe use of the product by your patients.** Casen Fleet trusts that the information provided will assist you in prescribing Fleet® Phospho-soda® for bowel cleansing in a safe and effective manner. Should you require further information, please call our Medical Affairs Department.

Sincerely,



Santiago Marco-Ibáñez, M.D.
International Medical Affairs Director
Laboratorios Casen Fleet, S.L.
+34 91 351 88 00
e-mail: smarco@casenfleet.com