

BLASTFAX

PCV7 Vaccine Recall – Unapproved Rubber Formulation in Some Syringe Tip Caps

Wyeth, now a part of Pfizer Inc, is voluntarily recalling the four lots of Prevnar®, Pneumococcal 7-valent Conjugate Vaccine, single dose pre-filled syringes. During a routine physical inspection of Prevnar® pre-filled syringes, Wyeth determined that a potential exists for syringes to have been distributed with a rubber formulation in the syringe tip caps that was not approved for use with Prevnar®. Wyeth performed a medical assessment and has concluded that the affected syringes present no health or safety risk to patients. Further, there would be no expected loss of potency and there is no need to revaccinate children who may have received a dose of Prevnar® from an affected syringe.

None of the vaccine being recalled is VFC Vaccine.

The affected products are:

PRODUCT: Prevnar® Pneumococcal 7-valent Conjugate Vaccine
(Diphtheria CRM₁₉₇ Protein)
SIZE: 0.5 mL single dose pre-filled syringe (10 per package)
NDC: 0005-1970-50 (10's)/0005-1970-49 (Singles)
LOT NOS.: E25197 (EXP 10/13), E28211 (EXP 10/13), E37556 (EXP 10/13), E38749 (EXP 11/13)
DISTRIBUTION: January 9, 2010 – March 3, 2010

Please examine your Wyeth inventory of Prevnar®, Pneumococcal 7-valent Conjugate Vaccine, single dose pre-filled syringes. If you have any product from the above lots, please remove it immediately from use. Contact Stericycle Inc. at 1-800-668-4391 and request a Return Kit from the Customer Service agent. Stericycle Inc. will subsequently send you a Return Kit with preprinted return address label(s), packing slip and instructions for returning the recalled product. You will receive credit for the returned merchandise.

If you have any further questions, please call your local Wyeth Representative or the Wyeth Product Quality Department at 1-800-999-9384. Thank you for your cooperation.

For questions or concerns regarding this blastfax or any other immunization information, please contact the Chapter's EPIC Immunization Program Director, Jill Ray at (404) 881-5081 or jray@gaaap.org.