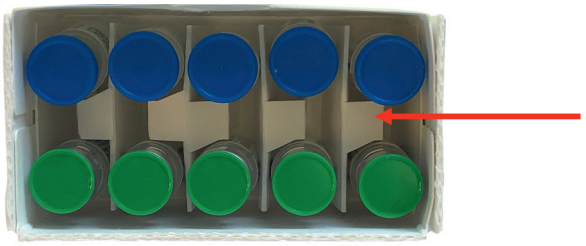
SANOFI PASTEUR

September 2018

Dear Health Care Provider/Customer

We are pleased to inform you that an enhancement has been made to the Pentacel® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate [Tetanus Toxoid Conjugate] Vaccine) packaging. Based upon customer feedback, the Pentacel vaccine box has been re-designed with separators between the vials to help reduce the vials from rubbing against each other and resulting in any potential for cracking during shipping. The box is slightly bigger to accommodate the separators (Dimensions: 3 3/8" wide, 2" high and 1 7/8" deep).

New Design

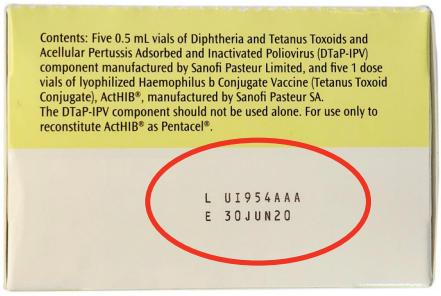


Old Design

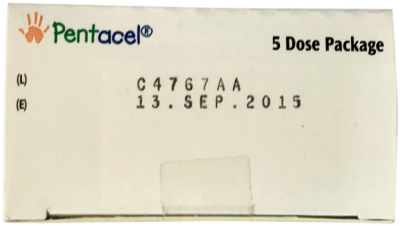
You will also notice two additional changes to the Pentacel vaccine packaging.

1) The lot number on the Pentacel vaccine box will have an additional alpha character. This simply denotes where the vaccine has been packaged. The lot numbers on the vials themselves have not changed. This does not impact the way lot numbers are recorded today.

Updated Lot Number



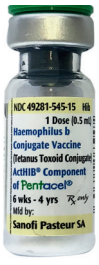
Old Lot Number



2) The label on the ActHIB (Haemophilus b Conjugate [Tetanus Toxoid Conjugate] Vaccine) vial is now vertical vs. horizontal. This does not impact the way lot numbers are recorded today.

New Label

Old Label



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We are excited to share this great news and that Sanofi Pasteur has begun to ship Pentacel vaccine lots with these changes. Over the coming months we will fully transition to this new packaging design.

Should you have any additional questions, please contact Sanofi Pasteur at 1-800-VACCINE (1-800-822-2463).

IMPORTANT SAFETY INFORMATION FOR PENTACEL VACCINE

Contraindications to vaccination with Pentacel vaccine include: a severe allergic reaction (eg, anaphylaxis) after a previous dose of Pentacel vaccine, any ingredient of Pentacel vaccine, or any other diphtheria toxoid-, tetanus toxoid-, pertussis antigen-containing vaccine, inactivated poliovirus vaccine, or *Haemophilus influenzae* type b vaccine; encephalopathy within 7 days after a previous dose of a pertussis antigen-containing vaccine with no other identifiable cause; or a progressive neurologic disorder.

Carefully consider benefits and risks before administering Pentacel vaccine to persons with a history of: fever ≥105°F, hypotonic-hyporesponsive episode (HHE), or persistent, inconsolable crying lasting ≥3 hours within 48 hours after a previous pertussis antigen-containing vaccine; seizures within 3 days after a previous pertussis antigen-containing vaccine; or adverse events after a previous dose of Pentacel vaccine or receipt of any other tetanus toxoid-, diphtheria toxoid-, or pertussis antigen-containing vaccine.

If Guillain-Barré syndrome has occurred within 6 weeks following receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following Pentacel vaccine.

For infants and children with a history of previous seizures, an antipyretic may be administered (in the dosage recommended in its prescribing information) at the time of vaccination with Pentacel vaccine and for the next 24 hours.

Apnea following intramuscular vaccination has been observed in some infants born prematurely.

The most common local and systemic adverse reactions to Pentacel vaccine include redness, swelling, and tenderness at the injection site; fever, fussiness, and abnormal crying. Other adverse reactions may occur. Vaccination with Pentacel vaccine may not protect all individuals.

INDICATION FOR PENTACEL VACCINE

Pentacel vaccine is indicated for active immunization against diphtheria, tetanus, pertussis, poliomyelitis, and invasive disease due to *H influenzae* type b. Pentacel vaccine is approved for use as a 4-dose series in children 6 weeks through 4 years of age (prior to fifth birthday).

Before administering Pentacel vaccine, please see accompanying full Prescribing Information.

Regards,

Brett Sarnoff

Brett Sarnoff
Head of Pediatric Marketing

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