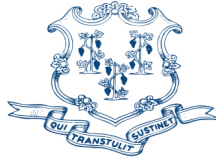


# STATE OF CONNECTICUT

## DEPARTMENT OF PUBLIC HEALTH

Manisha Juthani, MD  
Commissioner



Ned Lamont  
Governor  
Susan Bysiewicz  
Lt. Governor

### Immunization Program

**TO:** All CVP Providers

**FROM:** Mick Bolduc 

Vaccine Coordinator-Connecticut Vaccine Program (CVP)

**DATE:** April 20, 2022

**SUBJECT:** Switch to Pre-filled Syringes for Quadracel™ & Vaxelis™ Vaccines

The primary purpose of this communication is to inform you that the CVP will be switching from single dose vials to pre-filled syringes for both Quadracel™ & Vaxelis™ vaccines.

#### **Quadracel™ Pre-filled Syringes**

Beginning June 1, 2022 the CVP will be transitioning over from single dose vials to pre-filled syringes for Sanofi's DTaP/IPV combination vaccine Quadracel™. Quadracel™ will be available in new prefilled syringes made without natural rubber latex. Quadracel™ will also be changing the source of IPV antigen from MRC-5 derived IPV to IPV that is derived from Vero cells, which aligns with that contained in the Sanofi Pasteur single-entity IPV vaccine (see below for more information). The NDC # for the Quadracel™ pre-filled syringe is 49281-0564-15. If you will be ordering the pre-filled syringes, you must use up your existing inventory of single dose vials before transitioning over to the syringes.

#### **Vaxelis™ Pre-filled Syringes**

Beginning June 1, 2022 the CVP will be transitioning over from single dose vials to pre-filled syringes for Merck's DTaP/IPV/HiB/Hepatitis B combination vaccine Vaxelis™. The NDC # for the Vaxelis™ pre-filled syringe is 63361-0243-15. If you will be ordering the pre-filled syringes, you must use up your existing inventory of single dose vials before transitioning over to the syringes.

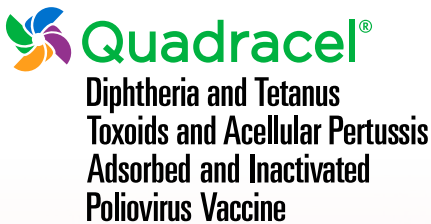
As always, if you have any questions, please feel free to contact me at (860) 509-7940.



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AVAILABLE TO ORDER SOON FROM QUADRACEL®

# NEW PREFILLED SYRINGES AND A CHANGE IN FORMULATION

## CHANGED FORMULA. SAME PROFILE.

### INDICATION

Quadracel is indicated for active immunization against diphtheria, tetanus, pertussis, and poliomyelitis. A single dose of Quadracel is approved for use in children 4 through 6 years of age as a fifth dose in the diphtheria, tetanus, pertussis vaccination (DTaP) series, and as a fourth or fifth dose in the inactivated poliovirus vaccination (IPV) series, in children who have received 4 doses of Pentacel® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate [Tetanus Toxoid Conjugate] Vaccine) and/or DAPTACEL® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed).

### WHAT WILL CHANGE?

Quadracel will be available in new prefilled syringes made without natural rubber latex. Quadracel will also be changing the source of IPV antigen from MRC-5-derived IPV (mIPV) to IPV that is derived from Vero cells (vIPV), which aligns with that contained in the Sanofi Pasteur single-entity IPV vaccine.<sup>1,2</sup>

### HOW DOES THIS IMPACT QUADRACEL?

This formulation of Quadracel retains the same dosing schedule, indication, safety, and immunogenicity data as the Quadracel formulation that is currently used.<sup>1,2</sup> Compared with single-entity alternatives, with Quadracel you can complete a patient's series of DTaP and IPV vaccination with one fewer injection.<sup>1-4</sup> Also, by using Sanofi Pasteur DTaP antigen-containing vaccines and Quadracel together, you can have continuity of DTaP antigens across the 5-dose series.<sup>1,5,6</sup>

See next page to learn what this means for you.

### IMPORTANT SAFETY INFORMATION

Contraindications to vaccination with Quadracel include: a severe allergic reaction (e.g., anaphylaxis) to any ingredient of Quadracel or following any other diphtheria toxoid-, tetanus toxoid-, or pertussis antigen-containing vaccine, or inactivated poliovirus vaccine; encephalopathy within 7 days of a previous dose of a pertussis antigen-containing vaccine that is not attributable to another identifiable cause; or a progressive neurologic disorder.

Please see continued Important Safety Information on the back of this piece. Please see the full Prescribing Information for Quadracel ([49281-562-10](tel:49281-562-10) and [49281-564-10/15](tel:49281-564-1015)).

Quadracel is part of a larger Sanofi Pasteur pediatric portfolio committed to helping protect your eligible patients against vaccine-preventable disease.<sup>1</sup>



VISIT [QUADRACEL.COM](http://QUADRACEL.COM) >

# WHAT'S THE DIFFERENCE?<sup>1,2</sup>

## UPDATED Quadracel formulated with Vero cell-derived IPV<sup>2</sup>

Indication		No change	
<b>Presentation</b>		<b>Available to order soon in both prefilled syringes and vials</b>	
DTaP component		No change	
<b>IPV component</b>		<b>Sourced from Vero cell-line manufacturing process</b>	
Immunogenicity data*		No change	
Safety*		No change	
CPT code (reimbursement)		No change	
National Drug Code (NDC)	Quadracel Vials	Carton	49281-564-10
		Vial	49281-564-58
	Quadracel Syringes	Carton	49281-564-15
		Syringe	49281-564-88

\*The safety and immunogenicity data are based on IPV antigen grown in MRC-5 cell line.<sup>1,2</sup>

**Ask your Sanofi Pasteur sales representative to learn more and to place an order for Sanofi Pasteur vaccines.**

### IMPORTANT SAFETY INFORMATION (CONTINUED)

Carefully consider benefits and risks before administering Quadracel to persons with a history of: fever  $\geq 105^{\circ}\text{F}$ , hypotonic-hyporesponsive episode, or persistent, inconsolable crying lasting  $\geq 3$  hours within 48 hours after a previous pertussis antigen-containing vaccine; seizures within 3 days after a previous pertussis antigen-containing vaccine; Guillain-Barré syndrome occurring within 6 weeks of receipt of a prior vaccine containing tetanus toxoid; or adverse events after a previous dose of Quadracel or receipt of any other tetanus toxoid-, diphtheria toxoid-, or pertussis antigen-containing vaccine.

The most common local and systemic adverse reactions to Quadracel include pain, erythema, and edema at the injection site; myalgia, malaise, and headache. Other adverse reactions may occur.

Vaccination with Quadracel may not protect all individuals.

**Please see the full Prescribing Information for Quadracel ([49281-562-10](#) and [49281-564-10/15](#)).**

**Please use this resource to help educate staff in your office about the updated formulation of Quadracel. Please ensure the new NDCs are loaded into your Electronic Health Records system before administration. If you have any additional questions, please contact your Quadracel representative.**

**References:** **1.** Quadracel [Prescribing Information]. NDC No. 49281-564-10/15. Swiftwater, PA: Sanofi Pasteur Inc. **2.** Quadracel [Prescribing Information]. NDC No. 49281-562-10. Swiftwater, PA: Sanofi Pasteur Inc. **3.** Centers for Disease Control and Prevention. Recommended child and adolescent immunization schedule for ages 18 years or younger, United States, 2021. Accessed November 16, 2021. <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf> **4.** Mosley JF II, Smith LL, Parke CK, Brown JA, LaFrance JM, Clark PK. Quadracel: vaccination against diphtheria, tetanus, pertussis, and poliomyelitis in children. *P T.* 2016;41(4):238-253. **5.** Liang J, Wallace G, Mootrey G. Licensure of a diphtheria and tetanus toxoids and acellular pertussis adsorbed and inactivated poliovirus vaccine and guidance for use as a booster dose. *MMWR Morb Mortal Wkly Rep.* 2015;64(34):948-949. doi:10.15585/mmwr.mm6434a5 **6.** Data on file. Internal acellular pertussis antigen statement. Swiftwater, PA: Sanofi Pasteur Inc.

**SANOFI PASTEUR. Discovery Drive. Swiftwater, Pennsylvania 18370. [www.sanofi.us](http://www.sanofi.us)**

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