

CONVERSION OF PEDIACEL[®] VIAL TO PENTACEL[®] VIAL IN CANADA

Question and Answers

Q1. Are Pediacel[®] vaccine and the Pentacel[®] vaccine equivalent and interchangeable?

Both the Pediacel[®] vaccine and the Pentacel[®] vaccine are pentavalent vaccines used to protect against diphtheria, tetanus, pertussis, polio and Haemophilus influenzae type b (Hib) in children from the age of 2 months, and in children up to 6 years of age (prior to their 7th birthday).

Although there are differences in the presentation between Pediacel[®] and Pentacel[®], they are equivalent and interchangeable. See Q6 for a comparison table.

Q2. If an infant has received one or two doses of Pediacel[®], can the primary series be completed with Pentacel[®]?

Yes. As recommended by the National Advisory Committee on Immunization (NACI), "The routine primary immunization series of diphtheria toxoid, tetanus toxoid, pertussis, poliomyelitis, Haemophilus influenzae type b-containing vaccine should be completed with an appropriate combination vaccine from the same manufacturer whenever possible. However, if the original vaccine is unknown or unavailable, an alternative combination vaccine from a different manufacturer may be used to complete the primary series."

Q3. Are there any safety concerns with respect to Pediacel[®]?

No. there are no concerns with the safety and quality of the Pediacel[®] vaccine.

Q4. Will Pentacel[®] be offered at the same price as Pediacel[®]?

Yes. Per the terms of the current supply agreement with PSPC (Clause 1.13 – "In the event that the Contractor is unable to supply the work in accordance with the terms and conditions of the contract, whether as a result of vaccine discontinuation or for any other reason, the Contractor will provide a substitute product acceptable to the Identified User at a price no greater than firm unit price specified in Annex B"), Sanofi will begin supplying Pentacel[®] at the same price as Pediacel[®] in April 2024. The two products are interchangeable per NACI recommendation on Pertussis containing vaccines.

Q5. Although you are discontinuing the production of Pediacel[®] vaccine, can providers use their remaining inventory of this vaccine?

Yes. The doses of Pediacel[®] vaccine that will be distributed in 2024 can be used until the expiration date (please refer to the date listed on the packaging).

Q6. **What are the differences between Pediacel[®] and Pentacel[®]?**

Contents (for each 0.5 mL dose)	Pentacel[®]	Pediacel[®]
Active Ingredients		
Diphtheria toxoid	15 Lf	15 Lf
Tetanus toxoid	5 Lf	5 Lf
Acellular Pertussis:		
Pertussis toxoid (PT)	20 µg	20 µg
Filamentous Haemagglutinin (FHA)	20 µg	20 µg
Pertactin (PRN)	3 µg	3 µg
Fimbriae Types 2 and 3 (FIM)	5 µg	5 µg
Inactivated Poliovirus*		
Type 1 (Mahoney)	29 D-antigen units	40 D-antigen units
Type 2 (MEF1)	7 D-antigen units	8 D-antigen units
Type 3 (Saukett)	26 D-antigen units	32 D-antigen units
Haemophilus Influenza Type B:		
Purified Polyribosylribitol Phosphate Capsular Polysaccharide (PRP) of Haemophilus influenzae Type b	10 µg	10 µg
Binding protein	18 - 30 µg of Tetanus protein	18-30 µg of Tetanus protein
Format	Reconstituted product for injection	Suspension for injection
Other contents:		
Excipients:		
Aluminum Phosphate (adjuvant)	1.5 mg	1.5 mg
2-phenoxyethanol	0.6% v/v	0.6% v/v
Tween 80 (polysorbate 80)	<8.1 µg	≤ 0.1% w/v (by calculation)

Water for injection	q.s 0.5 mL	
Tris (hydroxymethyl) aminomethane	0.6 mg	
Sucrose	42.5 mg	
Manufacturing process residuals	Formaldehyde, Glutaraldehyde, Bovine Serum Albumin, Neomycin, Polymyxin B, Streptomycin Sulfate	Formaldehyde, Glutaraldehyde, Bovine Serum Albumin, Neomycin, Polymyxin B, Streptomycin

**Although the antigen content of Pediacel® and Pentacel® vaccines are the same, there are different test methods used to validate the IPV potency for each batch, hence the different values included in the table above.*

Lf – Limit of Flocculation

Q7. Does the difference in non-active excipients result in any patient impact?

No, differences in non-active excipients should not have any patient impact.

Q8. Who can I contact in case of any product-specific questions related to the new Pentacel?

In case of any further queries, please call our MedInfo team at 1-888-621-1146.

Resources:

- *Pediacel® Product Monograph*
- *Pentacel® Product Monograph*
- *NACI Statement on Pertussis Containing Vaccines*