

1 December 2024

Dear Healthcare Providers

Prevenar 20 Pediatric Indication now approved in Hong Kong, 19 November 2024

We are pleased to inform you of the recent approval of indication extension for Prevenar 20, a pneumococcal conjugate vaccine developed to provide broader protection against pneumococcal disease for pediatric through to adult population usage. *No changes in other registered particulars.

Updated Indication Approved/ Change

Department of Health, DOH has approved the use of Prevenar 20 for the prevention of pneumococcal disease in 6 weeks and above. With the latest update we will have the following indication for Prevenar 20.

- Active immunisation for the prevention of invasive disease, pneumonia, and acute otitis media caused by *Streptococcus pneumoniae* in infants, children, and adolescents from 6 weeks to less than 18 years of age.
- Active immunisation for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals 18 years of age and older.

This approval is based on robust clinical trial data demonstrating the vaccine's immune response and safety in this population.

Key Highlights

- **Expanded Protection**: Prevenar 20 now includes additional serotypes, offering protection against a wider range of pneumococcal serotypes, coverage of 7 more serotypes (8, 10A, 11A, 12F, 15B, 22F, 33F) compared to Prevenar 13.
- *Immune response:* Post Dose 4 clinical trials have shown that 13 matched serotypes in the Prevenar 20 group generally shows comparable OPA GMTs in Prevenar 13. The additional 7 serotypes showed substantially higher OPA GMTs in Prevenar 20 group than Prevenar 13 group. Boosting of IgG and OPA GMTs post dose 4 indicate that a memory response was elicited by 3 primary doses.
- **Safety:** The vaccine has been well-tolerated, with a safety profile comparable to controlled vaccine-Prevenar 13. Common side effects include mild injection-site reactions and transient systemic symptoms.

Vaccination Schedule

The updated Prevenar 20 with pediatric indication is recommended for administration as follows:

Series	Schedule
Infants 6 weeks to 15 months of age	Primary Doses (each of 0.5mL) First dose usually given at 2 months of age(or as early
4-dose series (3 primary dose + 1 booster dose)	as 6 weeks) and with an interval of at least 4 weeks between doses.
	Booster dose of 0.5mL: Between 11-15 months of age
Unvaccinated Children age 12 months to 24 months of age	2 doses of 0.5mL with an interval of at least 8 weeks between doses
Unvaccinated Children above 2 years of age	1 single dose of 0.5mL

Product Insert/ Educational Resources

Please refer to the following QR code for the latest approved PI on your application on your patients.



https://labeling.pfizer.com/ShowLabeling.aspx?id=19588

If you have any questions or need further assistance, please do not hesitate to contact our medical information department at <u>HKMedinfo.Pfizer@Pfizer.com</u>. We are here to support you in providing the best care for your patients.

Thank you for your continued dedication to improving public health.

Yours faithfully, **PFIZER CORPORATION HONG KONG LIMITED**

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