Synflorix®
Pneumococcal polysaccharide conjugate vaccine, 10 valent adsorbed

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Introducing *Synflorix*® – fully funded pneumococcal conjugate vaccine for New Zealand children[1]

GlaxoSmithKline NZ Ltd would like to inform you that *Synflorix*® has replaced *Prevenar*® as the pneumococcal vaccine on the National Immunisation Schedule as of 1st July 2011 and will be available once existing stocks of *Prevenar*® have been used.[1]

Synflorix is the next generation pneumococcal conjugate vaccine for immunisation against invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae*.[2,3] *Synflorix* is an important advance because it provides broader coverage of disease relevant to New Zealand children than the vaccine it is replacing.[1,3]

Please find enclosed a Fact Sheet on *Synflorix*, which also details the Ministry of Health's implementation process. We invite you and your colleagues to review this resource and ask you to retain it as a quick reference guide in your practice.

Children who have already been fully immunised with *Prevenar* will not require additional doses of pneumococcal vaccine.[1] These children are at less risk of pneumococcal disease, since the highest rates of invasive pneumococcal disease are in children younger than 2 years.[6,7]

Synflorix has been approved for use in 100 countries around the world and has also been endorsed by the WHO based on its safety and potential to prevent disease.[4,5] In the past year, over 39 million doses of *Synflorix* have been distributed worldwide.[4]

For further information on *Synflorix*, please also refer to:

- The *Synflorix* Data Sheet (www.medsafe.govt.nz)
- The Ministry of Health Immunisation Handbook (http://www.moh.govt.nz/moh.nsf/Files/immunisation2011/$file/0-intro-v2.pdf)
- The Immunisation Advisory Centre website (www.immune.org.nz).

Yours sincerely,

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References:

1. Ministry of Health. Update: National Immunisation Schedule changes from 1 July 2011. Available at: http://www.moh.govt.nz/moh.nsf/indexmh/immunisation. Accessed 11 May 2011.
2. Dagan R, Frasch C. *Pediatr Infect Dis J*. 2009;28 Suppl:S63–S65.
3. *Synflorix* Data Sheet, GSK New Zealand.
4. GlaxoSmithKline. Data on file. Global sales data. 2011.
5. World Health Organization. WHO prequalification of *Synflorix*®: Pneumococcal (conjugate) 1dose vial. Geneva, Switzerland: WHO; 30 October, 2009. Available at: http://www.who.int/immunization_standards/vaccine_quality/PQ_192_Pneumococcal_GSK_1dose/en/ Accessed 2 July 2011.
6. Jackson C. *Serious Pneumococcal Disease in New Zealand*. Report prepared for the Immunisation Advisory Centre. July 2007. Available at: www.immune.org.nz. Accessed 7 July 2011.
7. Voss L et al. Invasive pneumococcal disease in a pediatric population, Auckland, New Zealand. *Pediatr Infect Dis J* 1994;13(10):873–878.

TAPS DA4311IG/11JL/247

* *Prevenar* (pneumococcal polysaccharide conjugate vaccine, 7-valent adsorbed) is a trademark of Pfizer NZ.

Synflorix®
Pneumococcal polysaccharide conjugate vaccine, 10 valent adsorbed

Synflorix® (10-valent adsorbed pneumococcal polysaccharide conjugate vaccine) is an injection for intramuscular use only. *Synflorix* is available on the National Immunisation Schedule and is a **prescription medicine** for active immunisation of infants and children from the age of 6 weeks up to 5 years against disease caused by *Streptococcus pneumoniae* serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, and 23F (including invasive disease, pneumonia, and acute otitis media). The recommended immunisation schedule consists of three doses beginning at 6 weeks of age, with an interval of at least 1 month between doses, plus a booster dose at least 6 months after this primary series. Each 0.5mL dose contains 1mcg of pneumococcal polysaccharide serotypes 1, 5, 6B, 7F, 9V, 14, and 23F and 3mcg of pneumococcal polysaccharide serotypes 4, 18C, and 19F adsorbed onto 0.5mg aluminium phosphate. *Synflorix* also contains approximately 13mcg of protein D carrier protein, approximately 8mcg of tetanus toxoid carrier protein, and approximately 5mcg of diphtheria toxoid carrier protein. **Contraindications:** known hypersensitivity to any component of the vaccine. **Precautions:** As with all injectable vaccines, provide appropriate supervision against rare anaphylactic events. Postpone in those with acute severe febrile illness (deferral not required with minor infections, e.g. a cold). Use caution with coagulation disorders. As with all vaccines a protective immune response may not be elicited in all vaccinees. Safety and immunogenicity data not available in those with underlying medical conditions predisposing to pneumococcal infection (e.g. sickle cell disease, splenic dysfunction, HIV). Children with impaired immune response (e.g. use of immunosuppressive therapy, genetic defect, HIV infected) may have a reduced immune response to vaccination. Data suggest that the use of prophylactic paracetamol might reduce the immune response to pneumococcal vaccines; the clinical relevance of this observation remains unknown. **Common side effects:** pain, redness, swelling, and induration at injection site; fever; drowsiness; loss of appetite; and irritability. As with some other vaccines, an increase in reactogenicity was reported after booster vaccination compared to the primary course. **Interactions:** immune responses and the safety profiles of the coadministered vaccines were unaffected, with the exception of the inactivated poliovirus type 2 vaccine, for which inconsistent results were observed across studies. No interference was observed with meningococcal conjugate vaccines irrespective of the carrier protein (CRM197 and TT conjugates). Enhancement of antibody response to diphtheria toxoid and tetanus toxoid was observed. Before prescribing *Synflorix*, please review the full Data Sheet at www.medsafe.govt.nz. *Synflorix* is a trade mark of the GlaxoSmithKline group of companies. Marketed by GlaxoSmithKline NZ Limited, Auckland. TAPS DA4311IG/11JU/232. H&T GSK0596.

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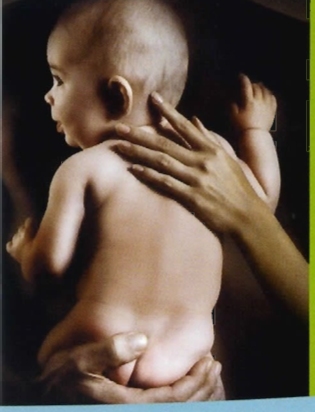

SYNFLORIX® FACT SHEET

Synflorix is fully funded and will replace *Prevenar*® on the Immunisation Schedule from 1 July 2011.[1]

Synflorix will be available once existing stocks of *Prevenar* have been used.[2]

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Introducing *Synflorix*

- *Synflorix* is the next generation pneumococcal conjugate vaccine for immunisation against invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae*.[3,4]
- *Synflorix* broadens coverage of severe infectious pneumococcal disease in NZ. It contains three additional serotypes – 1, 5, and 7F – which are not in *Prevenar*.[3-6]
- The inclusion of these particular serotypes is an important advance because they cause nearly a quarter of cases of invasive disease in NZ infants, and disproportionately affect Maori and Pacific children.[7]
- *Synflorix* also induces immune responses to a further two serotypes, 19A and 6A, which are not included in the vaccine.[4,8,†]
- *Synflorix* is the only vaccine designed to stimulate immune responses against the two leading causes of bacterial acute otitis media.[4,6,9,†]
- Protein D is the main carrier protein in *Synflorix* and is from the surface of a bacteria called non-typeable *Haemophilus influenzae* (NTHi).[3]

Administration

- The recommended schedule for *Synflorix* coincides with the current National Immunisation Schedule, so children will still receive their pneumococcal immunisations at ages 6 weeks, 3 months, 5 months and 15 months.[1,2]
- Children who have received one or more doses of *Prevenar* can be switched to *Synflorix* at any point in their schedule to complete their pneumococcal vaccine course.[2]
- Children who switch from *Prevenar* to *Synflorix* should develop protection against the seven strains in both vaccines and also benefit from the additional three serotypes.[2,9]
- *Synflorix* can be coadministered with vaccines on the National Immunisation Schedule, and also with rotavirus and varicella vaccines.[4]

Safety

- *Synflorix* is generally well-tolerated, with a safety profile that is similar to *Prevenar* and commonly coadministered vaccines.[4,10]
- The most common adverse reactions are local site reactions (pain, redness and swelling) and general reactions of drowsiness, irritability, loss of appetite and fever.[4]

Global Use

- *Synflorix* is approved for use in 83 countries and has also been endorsed for use by the WHO based on its safety and potential to prevent disease.[11,12]
- *Synflorix* is being used as part of national immunisation programmes in Austria, Brazil, Finland, Hong Kong, Mexico, Sweden, Taiwan, the Netherlands and in Northern Territory (Australia).[11]
- In the past year, over 7 million doses of *Synflorix* have been distributed worldwide.[11]

Next generation protection[3,15]

Otitis Media

- Together, *S. pneumoniae* and NTHi cause up to 80% of cases of bacterial otitis media in children.[13]
- Every year in NZ, otitis media causes approximately 5,000 children aged <5 years to be admitted to hospital, and 75,000 to visit their GP.[14]

Composition

- *Synflorix* contains purified polysaccharides from ten serotypes of *S. pneumoniae*, and Protein D from NTHi as a carrier protein.[4]
- *Synflorix* also contains aluminium phosphate, tetanus toxoid and diphtheria toxoid carrier proteins, sodium chloride, and water.[4]
- *Synflorix* does not contain thiomersal or any other preservative.[4]
- *Synflorix* is not a live vaccine – administration cannot cause pneumococcal disease.[4]

Storage

- Refrigerate at +2°C to +8°C. Do not freeze.
  Store in the original package to protect from light.[4]

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† *Synflorix* is not indicated for immunisation against disease caused by non-vaccine serotypes or NTHi.[4] However, the approved labelling for *Synflorix* reviews data from a comprehensive clinical research programme, showing immune responses to pneumococcal serotypes 6A and 19A, and to Protein D from NTHi.[4]

1. Ministry of Health. Announcement – Changes to the National Immunisation Schedule for July 2011. Available at: http://www.moh.govt.nz/moh.nsf/ indexmh/immunisation. Accessed 11 May 2011. **2.** Ministry of Health. Update: National Immunisation Schedule changes from 1 July 2011. Available at: http://www.moh.govt.nz/moh.nsf/indexmh/immunisation. Accessed 11 May 2011. **3.** Dagan R, Frasch C. *Pediatr Infect Dis J.* 2009;28:S63–S65. **4.** *Synflorix®* Data Sheet, GSK New Zealand. **5.** *Prevenar®* Data Sheet, Pfizer New Zealand. **6.** Schuerman L et al. *Vaccine.* 2009;27:5748–54. **7.** Institute of Environmental Science and Research Ltd. *Invasive pneumococcal disease in New Zealand, 2009.* ESR; 2010. Available at: www.surv.esr.cri.nz/PDF_surveillance/IPD/2009/2009AnnualIPDRpt.pdf. Accessed 20 March 2011. **8.** Vesikari T et al. *Pediatr Infect Dis J.* 2009;28:S66–76. **9.** Ministry of Health; *Immunisation Handbook 2011.* Wellington: Ministry of Health; 2011. **10.** Chevallier B et al. *Pediatr Infect Dis J.* 2009;28:S109–118. **11.** GSK. Data on file. Global sales data. 2011. **12.** WHO prequalification of *Synflorix*: Pneumococcal (conjugate) 1 dose vial. WHO; 30 October, 2009. Available at: www.who.int/immunization_standards/vaccine_quality/PQ_192_Pneumococcal_GSK_1dose/en/ Accessed 2 January 2011. **13.** Leibovitz E et al. *Pediatr Infect Dis J.* 2004;23:1142–52. **14.** Milne RJ, Vander Hoorn S. *Report to the New Zealand Ministry of Health.* November 2009. **15.** Tregnaghi M et al. *29th Annual Meeting of the European Society for Paediatric Infectious Diseases;* The Hague, Netherlands: 7–11 June 2011. Available at: http://www.abstractserver.com/ESPID2011/planner/index.php. Accessed on 7 May 2011.

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Next generation protection[3,15]