



Synflorix® – Vaccine protection against *S. pneumonia* and Non-Typeable *Haemophilus influenzae*

Approved indication

Synflorix® is a polysaccharide conjugate vaccine that contains 10 *Streptococcus pneumoniae* serotypes (1, 4, 5, 6B, 7F, 9V, 14, 19F and 23F), eight of which are conjugated to protein D, a highly conserved surface protein from Non-Typeable *Haemophilus influenzae* (NTHi).^{1,2}

Synflorix® is indicated for active immunisation of infants and children from six weeks up to two years of age against disease caused by *Streptococcus pneumoniae* vaccine serotypes as above and against acute otitis media caused by Non-Typeable *Haemophilus influenzae*.¹

Mode of action and clinical efficacy

Synflorix® induces appropriate immune responses to protect against invasive pneumococcal disease (i.e. meningitis, bacteraemia and pneumonia) caused by vaccine serotypes.¹ Clinical trials have demonstrated significant antibody response (ELISA) as well as functional antibodies (as measured by opsonophagocytic assay [OPA]) to all vaccine serotypes one month after completion of primary vaccination.

The protective efficacy against the first episode of acute otitis media (AOM) was evaluated in the large, randomised, double-blind Pneumococcal Otitis Media Efficacy Trial (POET).

- Vaccine efficacy against the first episode of AOM caused by pneumococcal serotypes was 52.6%.²
- Vaccine efficacy against the first episode of AOM caused by NTHi was above 30%.²
- The overall incidence of AOM was reduced by 33.6%.²

Dosage

Primary vaccination in infants six weeks to six months of age consists of a total of three doses administered at least one month apart. This should be followed by a booster dose at least six months after the last primary dose, preferably between 12 and 15 months of age.²

The vaccine may also be administered to previously unvaccinated infants under 23 months of age as follows^{1,2}:

- 7–11 months of age: Two doses administered at least one month apart, followed by a third dose, at least two months after the last dose and preferably in the second year of life.
- 12–23 months of age: Two doses administered at least 2 months apart.

The vaccine is available as a 0.5 ml suspension and is administered by intramuscular injection into the thigh muscle in infants or into the deltoid muscle of the upper arm in young children.

Precautions

General

Synflorix® should not be administered to individuals with a known hypersensitivity to any component of the vaccine. As with all injectable vaccines, appropriate medical supervision should be available in the event of a rare anaphylactic reaction following the administration of the vaccine.¹ The administration of the vaccine should be postponed in children suffering from acute severe febrile illness.¹

Major adverse effects

The tolerability profile of Synflorix® is similar to that of the 7-valent pneumococcal conjugate vaccine.² The most common adverse events include redness, swelling and pain at the injection site as well as irritability, drowsiness, fever and loss of appetite.²

Drug interactions

Synflorix® can be co-administered with other childhood vaccines such as diphtheria, tetanus, pertussis (whooping cough), *Haemophilus influenzae* type b, inactivated polio, hepatitis B, measles, mumps and rubella, varicella (chickenpox), oral polio and rotavirus vaccines.²

Cost: SEP (Incl VAT)

Synflorix® 0.5 ml prefilled syringe: R542.48

Aspen Pharmacare

Patient information

Synflorix® provides protection against two major causative bacteria for invasive pneumococcal diseases such as meningitis, bacteraemia and pneumonia in children as well as against non-invasive disease i.e. acute otitis media.

Normally, the child should receive two or three doses of vaccine. Each dose will be given on separate occasions.

Conclusion

Synflorix® is the first conjugate vaccine containing *S. pneumoniae* polysaccharide antigens with Non-Typeable *Haemophilus influenzae* protein D as the carrier protein. The vaccine shows high immunogenicity against all pneumococcal vaccine antigens and a clinically relevant protection against episodes of AOM caused by NTHi and *S. pneumoniae*.² □

References:

1. Synflorix Package Insert.
2. Croxtall JD, Keating GM. Pneumococcal polysaccharide protein-D conjugate vaccine (Synflorix; PHiD-CV). *Pediatr Drugs* 2009;11(5):349-357.

