Package leaflet: Information for the user

Synflorix suspension for injection in pre-filled syringe
Pneumococcal polysaccharide conjugate vaccine (adsorbed)

Read all of this leaflet carefully before your child receives this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for your child only. Do not pass it on to others.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Synflorix is and what it is used for

Synflorix is a pneumococcal conjugate vaccine. Your doctor or nurse will inject your child with this vaccine.

It is used to help protect your child from 6 weeks up to 5 years of age against:
a bacteria called '*Streptococcus pneumoniae*'. This bacteria can cause serious illnesses including meningitis, sepsis and bacteraemia (bacteria in blood stream) as well as ear infection or pneumonia.

How Synflorix works

Synflorix helps your body to make its own antibodies. The antibodies form a part of the immune system that will protect your child against these diseases.

2. What you need to know before your child receives Synflorix

Synflorix should not be given if:

- your child is allergic to the active substance, or any of the other ingredients of this vaccine (listed in section 6).
  Signs of an allergic reaction may include itchy skin rash, being short of breath and swelling of the face or tongue.
- your child has a severe infection with a high temperature (over 38 °C). If this applies to your child then the vaccination will be postponed until your child is feeling better. A minor infection such as a cold should not be a problem. However, talk to your doctor first.

Synflorix should not be given if any of the above applies to your child. If you are not sure, talk to your doctor or pharmacist before your child is given Synflorix.

Warnings and precautions

Check with your doctor or pharmacist before this vaccine is given if:
- your child has a bleeding problem or bruises easily.

In children as of 2 years of age, fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if your child fainted with a previous injection.

As with all vaccines, Synflorix may not fully protect all children who are vaccinated.

Synflorix will only protect against infections caused by the bacteria for which the vaccine has been developed.

Children with a weakened immune system (such as due to human immunodeficiency virus (HIV) infection or immunosuppressive therapy) may not get the full benefit from Synflorix.

If you are not sure, talk to your doctor or pharmacist before having Synflorix.

Children above 5 years old

For children above 5 years old safety and efficacy of the vaccine have not been established, therefore vaccination of these children is not recommended.

Other medicines and Synflorix

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, or if they have recently received any other vaccine. Synflorix may not work as well if your child is taking medicines that affect the immune system to fight infection.

Synflorix can be given at the same time as other childhood vaccines such as diphtheria, tetanus, pertussis (whooping cough), *Haemophilus influenzae* type b, oral or inactivated polio, hepatitis B, measles-mumps-rubella, varicella, oral rotavirus vaccines as well as meningococcal serogroup C and serogroups A, C, W-135, Y conjugate vaccines. A different place for the injection will be used for each vaccine.

Your doctor may ask you to give your child a medicine that lowers fever (such as paracetamol) before or immediately after Synflorix is given, especially in children being vaccinated with Synflorix and vaccines containing whole cell pertussis at the same time. It is also recommended to administer a medicine that lowers fever in children with convulsion disorders or with prior history of febrile convulsions.
However if your child has received paracetamol before or immediately after Synflorix is given, the obtained levels of antibodies may be slightly reduced. It is not known whether the reduction in antibody levels has an impact on the protection against pneumococcal disease.

Synflorix contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

3. How Synflorix is given

How the vaccine is given

Synflorix is always injected into a muscle. This is usually in the thigh or upper arm.

How much is given

Usually, your child (from 6 weeks to 6 months of age) will receive a course of 4 injections according to official recommendations or an alternative schedule may be used by the health care professional. It is important to follow the instructions from the doctor or nurse to complete the courses of injections.

- Each injection will be given at least one month apart except for the last injection (booster), which will be given at least 6 months after the third injection.
- The first injection may be given from the age of 6 weeks onwards. The last injection (booster) may be given from the age of 9 months onwards.
- You will be told when your child should come back for the next injections.

Preterm infants (born after 27 weeks and less than 37 weeks of pregnancy):
Your child (from 2 months to 6 months of age) will receive 3 injections with an interval of at least one month between each dose. At least six months after the last injection, your child will receive an additional injection (booster).

Infants aged 7 to 11 months will receive 2 injections. Each injection will be given at least one month apart. A third injection (booster) will be given in the second year of life with at least two months apart.

Children aged 12 months to 5 years will receive 2 injections. Each injection will be given at least two months apart.

Special populations:
Children from 6 weeks up to 5 years of age considered to be at a higher risk of pneumococcal infection (such as those with HIV infection, sickle cell disease or impaired or abnormal functioning of the spleen) may receive Synflorix. Please speak to your doctor for information on the number and timing of injections for your child.

If your child misses an injection

If your child misses an injection, it is important that you make another appointment. This is so that you and your doctor can talk about what steps need to be taken to protect your child.

If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Severe allergic reactions may very rarely occur (with up to 1 in 10,000 doses of the vaccine). These can be recognised by:
- raised and itchy rash (hives)
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing
- collapse

These reactions will usually occur before leaving the doctor's surgery. However, if your child gets any of these symptoms you should contact a doctor urgently.

Very common (these may occur with more than 1 in 10 doses of the vaccine)
- pain, redness and swelling where the injection is given
- high temperature of 38 °C or higher (fever)
- feeling sleepy
- feeling irritable
- loss of appetite

Common (these may occur with up to 1 in 10 doses of the vaccine)
- hardness where the injection is given

Uncommon (these may occur with up to 1 in 100 doses of the vaccine)
- itching, blood clot, bleeding or a small lump where the injection is given

- nausea, diarrhoea or feeling sick (vomiting)
- unusual crying
- temporarily stopping breathing (apnoea) if your child is born prematurely (before or at 28 weeks of pregnancy)
- headache
- skin rash
- diffuse swelling of the injected limb, sometimes involving the adjacent joint
- hives

Rare (these may occur with up to 1 in 1,000 doses of the vaccine)
- fits without temperature or due to high temperature (fever)
- allergic reactions such as skin allergies
- collapse (sudden onset of muscle floppiness), periods of unconsciousness or lack of awareness, and paleness or bluish skin discoloration

Very rare (these may occur with up to 1 in 10,000 doses of the vaccine)
- Kawasaki disease (major signs of the illness are for instance: fever, skin rash, swollen lymph glands, inflammation and rash of the mucous membranes of the mouth and throat)

Booster doses of Synflorix may increase the risk of side effects.
For children > 12 months of age, the risk of pain at the injection site may increase with increasing age.

In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccination.

Reporting of side effects

If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Synflorix

Keep this medicine out of the sight and reach of children.

- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store in a refrigerator (2 °C – 8 °C).
- Store in the original package in order to protect from light.
- Do not freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Synflorix contains

- The active substances are:

  One 0.5 ml dose contains:

Pneumococcal polysaccharide serotype 1[1,2]	1 microgram
Pneumococcal polysaccharide serotype 4[1,2]	3 micrograms

Pneumococcal polysaccharide serotype 5[1,2]	1 microgram
Pneumococcal polysaccharide serotype 6B[1,2]	1 microgram
Pneumococcal polysaccharide serotype 7F[1,2]	1 microgram
Pneumococcal polysaccharide serotype 9V[1,2]	1 microgram
Pneumococcal polysaccharide serotype 14[1,2]	1 microgram
Pneumococcal polysaccharide serotype 18C[1,3]	3 micrograms
Pneumococcal polysaccharide serotype 19F[1,4]	3 micrograms
Pneumococcal polysaccharide serotype 23F[1,2]	1 microgram

[1] adsorbed on aluminium phosphate 0.5 milligram Al^{3+} in total
[2] conjugated to protein D (derived from non-typeable *Haemophilus influenzae*) carrier protein 9–16 micrograms
[3] conjugated to tetanus toxoid carrier protein 5–10 micrograms
[4] conjugated to diphtheria toxoid carrier protein 3–6 micrograms

- The other ingredients are sodium chloride (see section 2 for further information) and water for injections

What Synflorix looks like and contents of the pack

- Suspension for injection in pre-filled syringe
- Synflorix is a turbid white suspension.
- Synflorix is available in pre-filled syringes for 1 dose with or without needles in packs of 1, 10 or 50.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu

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The following information is intended for healthcare professionals only:

A fine white deposit with a clear colourless supernatant may be observed upon storage of the pre-filled syringe. This does not constitute a sign of deterioration.

The content of the pre-filled syringe should be inspected visually both before and after shaking for any foreign particulate matter and/or abnormal physical appearance prior to administration. In the event of either being observed, discard the vaccine.

The vaccine should be allowed to reach room temperature before use.

The vaccine should be well shaken before use.

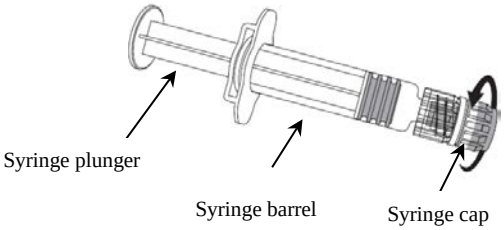
The vaccine is for intramuscular use only. Do not administer intravascularly.

If Synflorix is co-administered with other vaccines, different injection sites should be used.

Synflorix should not be mixed with other vaccines.

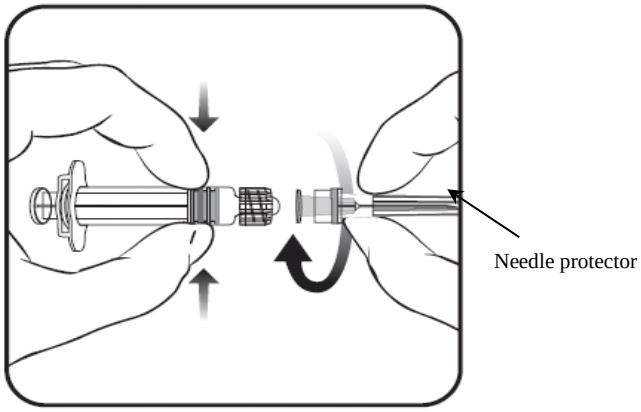
Instructions for administration of the vaccine presented in pre-filled syringe

1. Holding the syringe **barrel** in one hand (avoid holding the syringe plunger), unscrew the syringe cap by twisting it anticlockwise.



2. To attach the needle to the syringe, twist the needle clockwise into the syringe until you feel it lock.

3. Remove the needle protector, which on occasion can be a little stiff.



Any unused product or waste material should be disposed of in accordance with local requirements.