SYNFLORIX

Pneumococcal polysaccharide conjugate vaccine, 10 valent adsorbed

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you use SYNFLORIX.

This leaflet answers some common questions about SYNFLORIX. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the expected benefits of your child having SYNFLORIX against the possible risks.

If you have any concerns about your child receiving SYNFLORIX, talk to your doctor or pharmacist.

Keep this leaflet with the vaccine.

You may need to read it again.

What is SYNFLORIX used for?

SYNFLORIX is a pneumococcal vaccine. SYNFLORIX helps protect your child against diseases such as: meningitis, blood infection, pneumonia and ear infection caused by ten types of the bacteria *Streptococcus pneumoniae*.

The vaccine works by helping the body to make its own antibodies, which protect your child against these diseases.

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

SYNFLORIX will only protect against infections caused by the groups of *Streptococcus pneumoniae* for which the vaccine has been developed.

Children with a weakened immune system, for example due to human immunodeficiency virus (HIV) infection, may not get the full benefit from SYNFLORIX.

Before your child receives SYNFLORIX

Synflorix should not be given if your child:

- has previously had any allergic reaction to SYNFLORIX, or any ingredient contained in SYNFLORIX. The active substances and other ingredients in SYNFLORIX are listed at the end of the leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Before your child is vaccinated, make sure your doctor knows if any of the following apply to your child

- has a severe infection with a high temperature. It might be necessary to postpone the vaccination until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first.
- has a bleeding problem or bruise easily.
- if your child has breathing difficulties, please contact your doctor. This may be more common in the first three days following vaccination if your child is born prematurely (before or at 28 weeks of pregnancy).

Fainting can occur following, or even before, any needle injection, therefore tell the doctor or nurse if your child fainted with a previous injection.

Using other medicines or vaccines

SYNFLORIX can be given at the same time as other childhood vaccines; in this case different injection sites should be used.

Please tell your doctor if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription or has recently received any other vaccine.

SYNFLORIX may not work as well if your child is taking medicines that reduce the effectiveness of their immune system to fight infection.

SYNFLORIX must not be used if:

- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Tell your doctor if:

You must tell your doctor if your child is:

- taking any other medicines, including medicines you buy without a prescription.

How SYNFLORIX is given

Infants from 6 weeks to 6 months of age
Usually, your child will receive three injections with an interval of at least one month between each one. The first injection can be given from the age of 6 weeks onwards. At least six months after the third injection, your child will receive an additional injection (booster).

Alternatively, your child may receive 2 injections with an interval of two months between injections. The first injection can be given from the age of 6 weeks onwards. At least six months after the second injection and from the age of 9 months onwards, your child will receive an additional injection (booster).

Preterm infants
Your child will receive three 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).

Previously unvaccinated older infants and children
- infants aged 7 to 11 months: your child will receive 2 injections with an interval of at least one month between injections. At least 2 months after the last injection and during his/her second year of life, your child will receive a third injection (booster).
- children aged 12 months to 23 months: your child will receive 2 injections with an interval of at least one month between injections. If an additional injection (booster) is necessary, the doctor will tell you.
- children aged 24 months to 5 years: your child will receive 2 injections with an interval of at least one month between injections.

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.

The doctor will give SYNFLORIX as an injection into the upper leg muscle in infants under 12 months of age. In children over 12 months of age, SYNFLORIX will usually be injected in the upper arm muscle.

The vaccine should never be given into a vein, artery or skin.

You will be informed when your child should come back for their next injection. If your child misses a scheduled injection, it is important that you make another appointment.

Make sure your child finishes the complete vaccination course. If not, your child may not be fully protected against the diseases.

If a dose is missed

If your child misses a scheduled injection, talk to your doctor or nurse and arrange another visit.

It is important that you follow the instructions of your doctor or nurse regarding return visits. If you forget to go back to your doctor at the scheduled time, ask your doctor for advice.

What are the side-effects?

Check with your doctor as soon as possible if you think your child is experiencing any side effects or allergic reactions after having SYNFLORIX, even if the problem is not listed below.

Contact your doctor immediately or take your child to the emergency department of your nearest hospital if any of the following happens:

- swelling of limbs, face, eyes, inside of nose, mouth, throat or ears, or severe skin reactions
- unusual tiredness or weakness that is sudden and severe

Like all medicines, SYNFLORIX can cause some side-effects, although not everybody gets them. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Side effects that occurred during clinical trials with SYNFLORIX are as follows:

Very common (these may occur in 1 in 10 doses or more of the vaccine):

- Pain, redness and swelling at the injection site
- Fever (38°C or higher)
- Drowsiness
- Irritability
- Loss of appetite

Common (these may occur in up to 1 in 10 doses of the vaccine):

- Hardness at the injection site

Uncommon (these may occur in up to 1 in 100 doses of the vaccine):

- Blood clot, bleeding and small lump at the injection site
- Diarrhoea, vomiting
- Unusual crying
- Temporarily stopping breathing (apnoea)
- Fits without fever or due to fever
- Headache
- Nausea
- Itchiness at the injection site
- Fever 40°C or higher has been observed in children age < 2 years
- Fever >39°C has been observed in children age 2 to 5 years
- Diffuse swelling of the injected limb, sometimes involving the nearby joint
- Rash

- If your child is more than 12 months of age when they receive their booster injection, they are more likely to experience reactions at the site of injection.

Rare (these may occur in up to 1 in 1,000 doses of the vaccine):

- Allergic reactions, such as skin rash or hives
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)

Very rare (these may occur with up to 1 in 10,000 doses of the vaccine)

Kawasaki disease (fever lasting for more than five days, associated with a rash on the trunk, peeling of the skin on the hands and fingers, swollen glands in the neck, red eyes, lips, throat and tongue).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Tell your doctor or pharmacist if you notice any side effects which are not mentioned here.

Do not be alarmed by this list of possible side-effects. Your child may not experience any of them.

How do I store SYNFLORIX?

SYNFLORIX is usually stored at the doctor's clinic or surgery, or at the pharmacy. But if you need to store SYNFLORIX always:

- Keep SYNFLORIX in a refrigerator stored between +2°C and +8°C. DO NOT FREEZE. Do not store it in the bathroom, or leave it in the car. Avoid exposing the vaccine to sunlight. HEAT CAN DESTROY THE VACCINE.

- Keep the vaccine out of reach and sight of children.

- Keep SYNFLORIX in the original pack in order to protect from light.

Ask your pharmacist what to do with any left over SYNFLORIX that has expired or has not been used.

Product description

What SYNFLORIX looks like

SYNFLORIX is a turbid white suspension for injection.

SYNFLORIX is available in pre-filled syringes or vials containing 0.5 mL for 1 dose.

Ingredients

SYNFLORIX contains polysaccharide derived from 10 *Streptococcus pneumoniae* serotypes.

Each 0.5 mL dose of SYNFLORIX contains 1 microgram of Pneumococcal polysaccharide serotypes 1, 5, 6B, 7F, 9V, 14 and 23F and 3 micrograms of Pneumococcal polysaccharide serotypes 4, 18C and 19F.

SYNFLORIX also contains 9-16 micrograms of Protein D carrier protein, 5-10 micrograms of tetanus toxoid carrier protein and 3-6 micrograms of diphtheria toxoid carrier protein and 0.5 milligrams of Aluminium phosphate.

SYNFLORIX does not contain a preservative.

SYNFLORIX also contains sodium chloride and water for injections.

Supplier:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland 1143
New Zealand

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

This leaflet was prepared on 21 November 2018.

The information provided applies only to: SYNFLORIX

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