SYNFLORIX
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

SYNFLORIX

Pneumococcal polysaccharide and Non-Typeable *Haemophilus influenzae* (NTHi) protein D conjugate vaccine, adsorbed.

Suspension for injection.

Sugar-free.

Read all of this leaflet carefully before SYNFLORIX is given to your child.

- SYNFLORIX is not for self-medication and must be administered by a healthcare professional
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist
- SYNFLORIX has been prescribed for your child only and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

6. Contents of the pack and other information.

1. What SYNFLORIX is and what it is used for:

SYNFLORIX is a vaccine given to children from 6 weeks of age up to 5 years of age to protect against diseases caused by some types of a bacteria called *Streptococcus pneumoniae*. These bacteria can cause serious illnesses including meningitis, blood infection, pneumonia and ear infection. This vaccine also helps protect your child against ear infection caused by another bacteria called non-typeable *Haemophilus influenzae*.

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

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

2. What you need to know before your child is given SYNFLORIX:

SYNFLORIX should not be given:

- if your child has previously had any allergic reaction to SYNFLORIX or any component contained in this vaccine. The active substances and other ingredients in SYNFLORIX are listed in section 6. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue.

Warnings and precautions:

Take special care with SYNFLORIX if your child:

- has a severe infection with a high temperature (over 38 °C). A minor infection such as a cold should not be a problem, but talk to your doctor first
- has a bleeding problem or bruises easily
- has any illness that weakens the immune system
- takes any medicine that can weaken the immune system

- 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).

Other medicines and SYNFLORIX:

Always tell your healthcare professional if your child is taking any other medicine. (This includes complementary or traditional medicines.)

Please tell your doctor if your child is taking or has recently taken paracetamol.

SYNFLORIX may be given at the same time your child receives other normally recommended vaccinations, 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.

SYNFLORIX can be given at the same time as other childhood vaccines. A different injection site will be used for each type of vaccine.

Pregnancy and breastfeeding and fertility:

SYNFLORIX is not intended for use in adults.

3. How SYNFLORIX is given:

The doctor or nurse will inject the recommended dose of vaccine.

Your doctor may wipe the skin with alcohol or other disinfecting agents and will let the skin dry before the injection.

SYNFLORIX will be injected into a muscle, usually in the thigh or upper arm.

Infants from 6 weeks of age 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 last injection and from the age of 9 months onwards, 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 last 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 7-11 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 5 years:*** your child will receive a total of 2 injections with an interval of at least two months 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 human HIV infection, sickle cell disease or impaired or abnoramal 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 you miss a dose of SYNFLORIX:

You will be informed when your child should come back for his/her 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.

4. Possible side effects:

SYNFLORIX can cause side effects.

Not all side effects reported for SYNFLORIX are included in this leaflet. Should your child's general health worsen or if your child experiences any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Severe allergic reactions which can be recognised by:

- raised and itchy rash
- swelling of the face or mouth (angioedema), causing difficulty in breathing
- a sudden drop in blood pressure and loss of consciousness.

These reactions will usually occur before leaving the doctor's surgery. However, if any of the above happens, tell your doctor immediately or go to the nearest nearest casualty department at your nearest hospital.

- These are all very serious side effects. If your child has them, your child may have had a very serious allergic reaction to SYNFLORIX.

Tell your doctor immediatey or go the casualty department at your nearest hospital if you notice the following:

- Kawasaki disease (major signs of the illness are for instance: fever which lasts for more than five days, associated with a rash on the trunk sometimes followed by a peeling of the skin on the hands and fingers, swollen glands in the neck, red eyes, lips, throat and tongue).

  ➔ These are all serious side effects. Your child may need urgent medical attention.

Frequent side effects include:

- drowsiness

- loss of appetite
- pain, redness, swelling at the injection site
- fever (38 °C or higher)
- irritability
- hardness at the injection site.

Less frequent side effects include:

- nausea (feeling sick), diarrhoea, vomiting (being sick)
- itching, blood clot, bleeding and small lump at the injection site
- unusual crying
- temporarily stopping breathing (apnoea)
- headache
- skin rash
- swelling larger than 5 cm where the injection was given
- hives.

If your child is more than 12 months of age when he/she receives his/her booster injection, he/she is more likely to experience reactions at the site of injection.

Other side effects include:

- fits without fever or due to 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 discolouration.

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.

Reporting of side effects:

If you get side effects, talk to your doctor or nurse. You can also report side effects to SAHPRA via the '**6.04 Adverse Drug Reaction Reporting Form,'** found inline under SAHPRA's publications: htpp://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SYNFLORIX.

5. How to store SYNFLORIX:

Store all medicines out of reach of children.

DO NOT FREEZE.

Store at +2 °C to +8 °C (in a refrigerator).

Discard if freezing has occurred.

Store in the original package in order to protect from light.

After first opening of the multidose vial, immediate use is recommended. If not used immediately, the vaccine should be stored in a refrigerator (+2 °C to +8 °C). If not used within 6 hours it should be discarded.

Do not use SYNFLORIX after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information:

What SYNFLORIX contains:

One dose (0,5 mL) contains 1 microgram of polysaccharide of serotypes $1^{1,2}$, $5^{1,2}$, $6B^{1,2}$, $7F^{1,2}$, $9V^{1,2}$, $14^{1,2}$ and $23F^{1,2}$; and 3 micrograms of serotypes $4^{1,2}$, $18C^{1,3}$ and $19F^{1,4}$.

[1] adsorbed on aluminium phosphate	0,5 milligram Al^{3+}
[2] conjugated to protein D (derived from Non-Typeable *Haemophilus influenzae*) carrier protein	13 micrograms
[3] conjugated to tetanus toxoid carrier protein	8 micrograms
[4] conjugated to diphtheria toxoid carrier protein	5 micrograms

The other ingredients are sodium chloride and water for injections.

What SYNFLORIX looks like and contents of the pack:

Cloudy liquid after shaking. A fine white deposit with a clear, colourless liquid may form upon storage.

SYNFLORIX is presented:

in pre-filled syringes for 1 dose (0,5 mL) with a plunger stopper (butyl rubber) and

with a rubber tip cap. Pack sizes of 1 or 10 with or without needles, or

- in vials for 1 dose (0,5 mL) with a grey stopper (butyl rubber) secured with an aluminium seal. Pack sizes of 1, 10 or 100, or
- in vials for 2 doses (1 mL) with a grey stopper (butyl rubber) secured with an aluminium seal. Pack size of 100.

The pre-filled syringes and vials are made of neutral glass type 1.

Holder of Certificate of Registration:

GlaxoSmithKline South Africa (Pty) Ltd

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