PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

BOOSTRIX TETRA Suspension for injection.

Diphtheria, tetanus, pertussis (acellular component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content).

Read all of this leaflet carefully before you or your child are given BOOSTRIX TETRA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, or your pharmacist, nurse or other healthcare provider.
- BOOSTRIX TETRA is not for self-medication and must be administered by a healthcare professional.

What is in this leaflet:

1. What BOOSTRIX TETRA is and what it is used for :

Booster vaccination:

BOOSTRIX TETRA is a vaccine used as a booster dose in children from 4 years onwards, teenagers and adults to prevent four diseases: diphtheria, tetanus (lockjaw), pertussis (whooping cough) and poliomyelitis (polio). The vaccine works by causing the body to produce its own protection (antibodies) against these diseases.

- **Diphtheria:** Diphtheria mainly affects the airways and sometimes the skin. Generally, the airways become inflamed (swollen) causing severe breathing difficulties and sometimes suffocation. The bacteria also release a toxin (poison), which can cause nerve damage, heart problems and even death.
- **Tetanus** (Lockjaw): Tetanus bacteria enter the body through cuts, scratches or wounds in the skin. Wounds that are especially prone to infection are burns, fractures, deep wounds or wounds contaminated with soil, dust, horse manure/dung or wood splinters. The bacteria release a toxin (poison), which can cause muscle stiffness, painful muscle spasms, fits and even death. The muscle spasms can be strong enough to cause bone fractures of the spine.
- **Pertussis** (Whooping cough): Pertussis is a highly infectious illness. The disease affects the airways causing severe spells of coughing that may interfere with normal breathing. The coughing is often accompanied by a 'whooping' sound, hence the common name 'whooping cough'. The cough may last for 1-2 months or longer. Pertussis can also cause ear infections, bronchitis which may last a long time, pneumonia, fits, brain damage and even death.
- **Poliomyelitis** (Polio): Poliomyelitis, sometimes called simply 'polio' is a viral infection that can have variable effects. Often it causes only a mild illness but in some people it causes permanent damage or even death. In its severest form, polio infection causes paralysis of

the muscles (muscles cannot move), including those muscles needed for breathing and walking. The limbs affected by the disease may be painfully deformed.

None of the ingredients in the vaccine can cause diphtheria, tetanus, whooping cough or poliomyelitis.

The use of BOOSTRIX TETRA during pregnancy will help to protect your baby from a whooping cough in the first few months of life before he/she receives the primary immunisation.

2. What you need to know before you take BOOSTRIX TETRA:

BOOSTRIX TETRA should not be administered to you:

- if you or your child have previously had any allergic reaction to BOOSTRIX TETRA, to any ingredient contained in this vaccine or to neomycin sulphate, polymyxin B sulphate (antibiotics), The active substances and other ingredients in BOOSTRIX TETRA are listed at the beginning of the leaflet. Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue
- if you or your child have previously had an allergic reaction to any vaccine against diphtheria, tetanus, pertussis (whooping cough) or poliomyelitis diseases
- if you or your child experienced problems of the nervous system (encephalopathy) within 7 days after previous vaccination with a vaccine against pertussis (whooping cough) disease
- if you or your child experienced a temporary reduction in blood platelets (which increases risk of bleeding or bruising) or problems with the brain or nerves after previous vaccination with a vaccine against diphtheria and/or tetanus.

Check with your doctor if you think any of these apply to you or your child.

Warnings and precautions:

- if you or your child have a severe infection with a high temperature (over 38 °C). A minor infection should not be a problem, but talk to your doctor first
- if after previously having BOOSTRIX TETRA or another vaccine against pertussis (whooping cough) disease, you or your child had any problems, especially:
  - a high temperature (over 40 °C) within 48 hours of vaccination
  - a collapse or shock-like state within 48 hours of vaccination
  - persistent crying lasting 3 hours or more within 48 hours of vaccination
  - seizures/fits with or without a high temperature within 3 days of vaccination
- if you or your child are suffering from neurological disorders, including infantile spasms, uncontrolled epilepsy or progressive encephalopathy (a disease of the brain)
- if you or your child have a bleeding problem or bruise easily
- if you or your child have a tendency to seizures/fits due to a fever, or if there is a family history of this
- if you or your child has long standing immune system problems due to any reason (including HIV infection). You or your child may still be given BOOSTRIX TETRA but the protection against infections after having the vaccine may not be as good as in children or adults with good immunity to infections
- collapse or periods of unconsciousness or lack of awareness, seizures or fits have occurred in children given other vaccines containing one or more of the active constituents of BOOSTRIX TETRA. They usually occur within two to three days after vaccination
- fainting can occur following, or even before, any needle injection, therefore, tell the doctor or nurse if you or your child fainted with a previous injection.

BOOSTRIX TETRA may not completely protect all people who are vaccinated.

Other medicines and BOOSTRIX TETRA:

- Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

  BOOSTRIX TETRA may not work as well if you or your child is taking medicines that reduce the effectiveness of the immune system to fight infection.
- BOOSTRIX TETRA can be given at the same time as some other vaccines. A different injection site will be used for each type of vaccine.

How to take BOOSTRIX TETRA with food and alcohol:

Not Applicable

Pregnancy and breast feeding and fertility:

The use of BOOSTRIX TETRA is not recommended during pregnancy. It is preferable to avoid use of BOOSTRIX TETRA during breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, your doctor will help you decide if you should receive BOOSTRIX TETRA, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machines:

BOOSTRIX TETRA is unlikely to produce an effect on the ability to drive and use machines.

BOOSTRIX TETRA contains neomycin sulphate, polymyxin B sulphate (antibiotics). and polysorbate 80

Please tell your doctor if you or your child has had an allergic reaction to these ingredients.

3. How to take BOOSTRIX TETRA

Do not share medicines prescribed for you with any other person.

Always take BOOSTRIX TETRA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.BOOSTRIX TETRA will be given as an injection into the muscle.

The vaccine should never be given into blood vessels.

You or your child will receive a single injection of BOOSTRIX TETRA.

Your doctor will verify if you or your child have previously received a vaccine against diphtheria, tetanus, pertusus and/or polio.

Your doctor will give you advice on repeat vaccination.

BOOSTRIX TETRA may be used in case of a suspected infection with tetanus, although additional provisions, i.e. elaborate wound dressing and/or application of Tetanus-Anti-Toxin will be taken as well to reduce the risk of manifestation of the disease.

If you take more BOOSTRIX TETRA than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Since a healthcare provider will administer BOOSTRIX TETRA, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side-effects:

BOOSTRIX TETRA can have side effects.

Not all side effects reported for BOOSTRIX TETRA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BOOSTRIX TETRA, please consult your health care provider for advice.

As with all injectable vaccines, severe allergic reactions (anaphylactic reactions) may occur. These can be recognised by:

- rashes that may be itchy or blistering
- swelling of the eyes and face
- difficulty in breathing or swallowing
- a sudden drop in blood pressure and loss of consciousness.

Such reactions may occur before leaving the doctor's surgery. However, if you get any of these symptoms you should contact a doctor immediately.

Side effects that occurred in children from the age of 4 to 9 years:

Frequent side effects include:

- pain, redness and swelling at the injection site
- sleepiness
- fever (more than 37,5 °C)
- swelling of the injected limb
- loss of appetite
- irritability
- headache
- bleeding at the injection site.

Less frequent side effects include:

- feeling sick (nausea), being sick (vomiting)
- swollen glands in the neck, armpit or groin (lymphadenopathy)
- sleeping problems
- apathy
- dry throat
- diarrhoea

- stomach pain or discomfort
- tiredness.

Co-administration with measles-mumps-rubella (MMR) or measles-mumps-rubella-varicella (MMRV) vaccines in children aged 3-6 years:

In studies where Boostrix Polio was given at the same time as a MMR or MMRV vaccine; skin rash and upper respiratory tract infection (including runny nose and sore throat) were commonly reported.

Fever, irritability, fatigue, loss of appetite and gastrointestinal disorders (including diarrhoea and vomiting) were reported more frequently (very common) than in studies where Boostrix Polio was given alone.

Side effects that occurred in adults, teenagers and children from the age of 10 years onwards:

Frequent side effects include:

- pain, redness and swelling at the injection site
- tiredness
- headache
- fever more than 37,5 °C
- bruising at the injection site.

Less frequent side effects include:

- oral herpes
- swollen glands in the neck, armpit or groin (lympadenopathy)
- decreased appetite
- tingling or numbness of the hands or feet (paraesthesia)
- sleepiness

- dizziness
- asthma
- itching
- joint pain (arthralgia)
- muscle pain (myalgia)
- fever more than 39 °C
- chills
- pain.

Other side effects:

The following side effects are not specific for any age group**:**

- swelling of the face, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)
- fits (with or without fever)
- hives (urticaria)
- hard lump at the injection site
- extensive swelling of the vaccinated limb
- unusual weakness (asthenia).

Additionally, the following side effects have been reported during clinical studies or routine use of Boostrix (GlaxoSmithKline Biological's booster vaccine against diphtheria, tetanus and pertussis):

Side effects that occurred in children from 4 to 9 years of age:

Frequent side effects include:

- disturbances in attention
- discharge with itching of the eyes and crusty eyelids (conjunctivitis)
- pain

- hard lump at the injection site.

Side effects that occurred in adults, teenagers and children from the age of 10 years onwards:

Frequent side effects include:

- generally feeling unwell
- nausea
- hard lump and abscess at the injection site.

Less frequent side effects include:

- upper respiratory tract infection
- sore throat and discomfort when swallowing (pharyngitis)
- fainting (syncope)
- cough
- diarrhoea
- vomiting
- excessive sweating (hyperhidrosis)
- skin rash
- joint or muscle stiffness
- flu-like symptoms, such as fever, sore throat, runny nose, cough and chills.

Following administration of vaccines against tetanus a temporary inflammation of the nerves, causing pain, weakness and paralysis in the extremities and often progressing to the chest and face have been reported very rarely (less than 1 in 10 000 doses of vaccine) (Guillain-Barré syndrome).

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

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse.

You can also report side effects to SAHPRA via the via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who- umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of BOOSTRIX TETRA.

5. How to store BOOSTRIX TETRA:

Store all medicines out of the sight and reach of children.

Store in a refrigerator (+2 °C to +8 °C). Do not freeze. Freezing destroys the vaccine.

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

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

6. Contents of the pack and other information:

What BOOSTRIX TETRA contains:

The active substances are:

Diphtheria toxoid	≥ 2 International Units (2,5 Lf)
Tetanus toxoid	≥ 20 International Units (5 Lf)
Bordetella pertussis antigens	
Pertussis toxoid	8 µg
Filamentous haemagglutinin	8 µg
Pertactin	2,5 µg
Inactivated poliovirus	
type 1 (Mahoney strain)	40 D-antigen unit
type 2 (MEF-1 strain)	8 D-antigen unit
type 3 (Saukett strain)	32 D-antigen unit

Adsorbed on aluminium hydroxide, hydrated	Total: 0,3 mg Al^{3+}
and aluminium phosphate	Total: 0,2 mg Al^{3+}

Aluminium hydroxide and aluminium phosphate are included in this vaccine as adjuvants. Adjuvants are substances included in certain vaccines to accelerate, improve and/or prolong the protective effects of the vaccine.

The other ingredients in BOOSTRIX TETRA are: Medium 199 (as stabilizer including amino acids, mineral salts and vitamins), sodium chloride and water for injections.

Residues:formaldehyde, neomycin and polymyxin

Sugar-free

What BOOSTRIX TETRA looks like and contents of the pack:

BOOSTRIX TETRA is a turbid liquid with a white deposit. The supernatant is colourless.

Pre-filled syringes: 1-dose pre-filled syringe with or without separate needles, pack sizes of 1 or 10.

Not all pack sizes may be marketed.

Holder of certificate of registration:

GlaxoSmithKline South Africa (Pty) Ltd

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