



## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

S2

### BOOSTRIX

Diphtheria, tetanus and pertussis (acellular component) vaccine

(adsorbed, reduced antigen(s) content)

Suspension for Injection

Sugar free

**Read all of this leaflet carefully before you or your child is vaccinated.**

BOOSTRIX 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 health care provider or pharmacist.

BOOSTRIX has been prescribed for you/your child only. Do not pass it on to others; it may harm them even if their symptoms are the same.

### What is in this leaflet:

1. What BOOSTRIX is and what it is used for
2. What you need to know before you receive BOOSTRIX
3. How to receive BOOSTRIX
4. Possible side effects

5. How to store BOOSTRIX

6. Contents of the pack and other information

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

BOOSTRIX is a vaccine used to protect you or your child against three diseases:

- **Diphtheria:** a serious bacterial infection that mainly affects the airways and sometimes the skin. The airways become swollen causing serious breathing problems and sometimes suffocation. The bacteria also release a poison. This 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 more likely to get tetanus infection are burns, fractures, deep wounds or wounds that have soil, dust, horse manure or wood splinters in them. The bacteria release a poison. This 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): a highly infectious illness that affects the airways. It causes severe coughing that may lead to problems with breathing. The coughing often has a “whooping” sound. The cough may last for one to two months or longer. Whooping cough can also cause ear infections, chest infections (bronchitis) which may last a long time, lung infections (pneumonia), fits, brain damage and even death.

BOOSTRIX helps you or your child’s body make its own protection (antibodies).

This will protect you and your child against the diseases mentioned above.



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

BOOSTRIX will only protect against infections caused by the pathogens mentioned above.

BOOSTRIX may not fully protect all children or people who are vaccinated.

## **2. What you need to know before receive BOOSTRIX:**

### **BOOSTRIX should not be administered to you:**

- if you or your child are allergic (hypersensitive) to BOOSTRIX or any other ingredients contained in BOOSTRIX. The active substances and other ingredients in BOOSTRIX are listed above in section 6. 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 or pertussis (whooping cough) 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:****Take special care with BOOSTRIX:**

Tell your doctor or healthcare professional before being given the injection if:

- if you or your child have a severe infection with a high temperature. In these cases, the vaccination will be postponed until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first
- if after previously having BOOSTRIX 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(s) 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.

Children or persons with a weakened immune system, for example due to HIV infection or due to medicines that suppress the immune system, may not get the full benefit from BOOSTRIX.

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. 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.

**Other medicines and BOOSTRIX:**

Always tell your healthcare professional if you are taking any other medicine.

This includes complementary or traditional medicines.

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

**Pregnancy and breastfeeding and fertility:**

If you are pregnant or breastfeeding, think that you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice, before you are given BOOSTRIX.

**Driving and using machines:**

BOOSTRIX is unlikely to affect your ability to drive or use machines. However, do not drive or use machines if you are feeling unwell.

**3. How to receive BOOSTRIX:**

You will not be expected to give yourself BOOSTRIX. It will always be given to you by a person who is qualified to do so.

You or your child will receive a single injection at an agreed date.

BOOSTRIX will be given as an injection into the muscle and should not be given into a vein.

BOOSTRIX may be used if you or your child are at risk of getting tetanus because of an injury.

Your doctor will verify if you or your child have previously received vaccines against diphtheria, tetanus and/or pertussis.

Repeat vaccination for diphtheria, tetanus and pertussis may be performed according to official recommendations. Your doctor will advise you.

#### **4. Possible side effects:**

BOOSTRIX can have side effects.

Not all side effects reported for BOOSTRIX are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using BOOSTRIX, please consult your doctor, pharmacist or other healthcare professional for advice.

**Allergic reactions:** If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- itchy rash of the hands and feet
- swelling of the eyes and face
- difficulty in breathing or swallowing
- sudden drop in blood pressure and loss of consciousness.

➔ These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BOOSTRIX. You may need urgent medical attention or hospitalisation. These reactions will usually occur before leaving the doctor's surgery. However, if you or your child gets any of these symptoms you should contact a doctor urgently.

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

Frequent side effects include:

- irritability
- sleepiness
- swelling, pain, redness where the injection was given, tiredness, fever (more than 37,5 °C)
- loss of appetite
- headache
- vomiting and diarrhoea.

Less frequent side effects include:

- upper respiratory tract infection
- disturbances in attention
- discharge with itching of the eyes and crusty eyelids (conjunctivitis)
- skin rash
- pain, hard lump where the injection was given.

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

Frequent side effects include:

- headache, dizziness
- swelling, pain, redness where the injection was given, tiredness, generally feeling unwell, fever (more than 37,5 °C), hard lump and abscess at the injection site
- nausea.

Less frequent side effects include:

- upper respiratory tract infection, sore throat and discomfort when swallowing (pharyngitis)
- swollen glands in the neck, armpit or groin (lymphadenopathy)

- fainting (syncope)
- cough
- diarrhoea, vomiting
- excessive sweating (hyperhidrosis), itching, skin rash
- joint stiffness, joint pain (arthralgia), muscle ache (myalgia)
- fever (more than 39 °C), flu-like symptoms, such as fever, sore throat, runny nose, cough and chills, pain.

**Other side effects that can occur in age group:**

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)
- seizures (with or without fever)
- hives (urticaria)
- large swelling of the injected limb, unusual weakness (asthenia).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects:**

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BOOSTRIX.

**5. How to store BOOSTRIX:**



BOOSTRIX should be stored at +2 C to +8 C. During transport, recommended conditions of storage must be respected.

**Do not freeze.** Discard if the vaccine has been frozen.

Store all medicines out of reach of children.

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

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What BOOSTRIX contains:

1 dose (0,5 ml) contains:

Diphtheria toxoid<sup>1</sup> not less than 2 International Units (IU) (2,5 Lf)

Tetanus toxoid<sup>1</sup> not less than 20 International Units (IU) (5 Lf)

*Bordetella pertussis* antigens

Pertussis toxoid<sup>1</sup> 8 µg

Filamentous Haemagglutinin<sup>1</sup> 8 µg

Pertactin<sup>1</sup> 2,5 µg

<sup>1</sup> adsorbed on aluminium hydroxide, hydrated (Al(OH)<sub>3</sub>) 0,3 mg Al<sup>3+</sup>

and aluminium phosphate (AlPO<sub>4</sub>) 0,2 mg Al<sup>3+</sup>

The other ingredients are sodium chloride and water for injections and residual amounts of formaldehyde, polysorbate 80, glycine.

Sugar-free.

### What BOOSTRIX looks like and contents of the pack:



BOOSTRIX is a turbid white suspension. Upon storage, a white deposit and clear supernatant can be observed.

Carton containing a clear, colourless glass (type 1) pre-filled syringe with a grey, butyl rubber, plunger stopper, with or without needles.

Carton containing a clear, colourless glass (type 1), 3 ml vial with a grey butyl rubber stopper and capped with natural, aluminium flip-off caps.

Pack sizes of 1, 10, 20, 25 and 50. Not all pack sizes may be marketed.

**Holder of Certificate of Registration:**

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

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