BOOSTRIX

Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content)
Suspension for injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

1 dose (0.5 mL) contains:

Diphtheria toxoid[1]	not less than 2 International Units (IU) (2.5 Lf)
Tetanus toxoid[1]	not less than 20 International Units (IU) (5 Lf)
Bordetella pertussis antigens	
Pertussis toxoid[1]	8 micrograms
Filamentous haemagglutinin[1]	8 micrograms
Pertactin[1]	2.5 micrograms
[1] adsorbed on aluminium hydroxide, hydrated ($Al(OH)_3$)	0.3 milligrams Al^{3+}
and aluminium phosphate ($AlPO_4$)	0.2 milligrams Al^{3+}

Boostrix is a turbid white suspension. Upon storage, a white deposit and clear supernatant can be observed. This is a normal finding.

CLINICAL INFORMATION

Indications

Boostrix is indicated for booster vaccination against diphtheria, tetanus and pertussis of individuals from the age of four years onwards (see *Posology*).

Boostrix is also indicated for passive protection against pertussis in early infancy following maternal immunization during pregnancy (see *Posology, Pregnancy* and *Pharmacodynamics*).

The use of ***Boostrix*** should be in accordance with official recommendations.

Dosage and Administration

Posology

A single 0.5 mL dose of the vaccine is recommended.

Boostrix can be given in accordance with the current local medical practices for booster vaccination with reduced-content combined diphtheria-tetanus vaccine, when a booster against pertussis is desired.

Boostrix can be administered to pregnant women between 27 and 36 weeks of pregnancy in accordance with official recommendations (see *Indications, Pregnancy* and *Pharmacodynamics*).

Boostrix may also be administered to adolescents and adults with unknown vaccination status or incomplete vaccination against diphtheria, tetanus and pertussis as part of an immunization series against diphtheria, tetanus and pertussis (see section *Pharmacodynamics*). Based on data in adults, two additional doses of a diphtheria and tetanus containing vaccine are recommended one and six months after the first dose to maximize the vaccine response against diphtheria and tetanus.

Repeat vaccination against diphtheria, tetanus and pertussis should be performed at intervals as per official recommendations (generally 10 years).

Boostrix can be used in the management of tetanus prone injuries in persons who have previously received a primary vaccination series of tetanus toxoid vaccine. Tetanus immunoglobulin should be administered concomitantly in accordance with official recommendations.

Method of administration

Boostrix is for deep intramuscular injection, preferably in the deltoid region (see also *Warnings and Precautions*).

Contraindications

Boostrix should not be administered to subjects with known hypersensitivity to any component of the vaccine (see *Quantitative and Qualitative Composition* and *List of Excipients*), or to subjects having shown signs of hypersensitivity after previous administration of diphtheria, tetanus or pertussis vaccines.

Boostrix is contraindicated if the subject has experienced an encephalopathy of unknown aetiology, occurring within 7 days following previous vaccination with pertussis-containing vaccine. In these circumstances pertussis vaccination should be discontinued and the vaccination course should be continued with diphtheria and tetanus vaccines.

Boostrix should not be administered to subjects who have experienced transient thrombocytopenia or neurological complications following an earlier immunization against diphtheria and/or tetanus (for convulsions or hypotonic-hyporesponsive episodes, see *Warnings and Precautions*).

Warnings and Precautions
As with other vaccines, administration of ***Boostrix*** should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection is not a contraindication.

Vaccination should be preceded by a review of the medical history (especially with regard to previous vaccination and possible occurrence of undesirable events) and a clinical examination.

If any of the following events are known to have occurred in temporal relation to receipt of pertussis-containing vaccine, the decision to give doses of pertussis-containing vaccines should be carefully considered:

- temperature of ≥40.0°C within 48 hours of vaccination, not due to another identifiable cause;
- collapse or shock-like state (hypotonic-hyporesponsiveness episode) within 48 hours of vaccination;
- persistent, inconsolable crying lasting ≥3 hours, occurring within 48 hours of vaccination;
- convulsions with or without fever, occurring within 3 days of vaccination.

In children with progressive neurological disorders, including infantile spasms, uncontrolled epilepsy or progressive encephalopathy, it is better to defer pertussis (Pa or Pw) immunization until the condition is corrected or stable. However, the decision to give pertussis vaccine must be made on an individual basis after careful consideration of the risks and benefits.

As with all injectable vaccines appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic reaction following the administration of the vaccine.

Boostrix should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. If in accordance with official recommendations, the vaccine may need to be administered subcutaneously to these subjects. With both routes of administration, firm pressure should be applied to the injection site (without rubbing) for at least two minutes.

A history or a family history of convulsions and a family history of an adverse event following DTP vaccination do not constitute contraindications.

Human Immunodeficiency Virus (HIV) infection is not considered as a contraindication for diphtheria, tetanus and pertussis vaccination. The expected immunological response may not be obtained after vaccination of immunosuppressed patients.

Extremely rare cases of collapse or shock-like state (hypotonic-hyporesponsiveness episode) and convulsions within 2 to 3 days of vaccination have been reported in DTPa and DTPa combination vaccines.

Boostrix **should under no circumstances be administered intravenously.**

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

Interactions

Boostrix can be given concomitantly with any of the following monovalent or combination vaccines: unadjuvanted inactivated seasonal influenza vaccines, human papilloma virus vaccines, meningococcal serogroups A, C, W-135 and Y (MenACWY) conjugate vaccines. Data have shown no clinically relevant interference in the antibody response to each of the vaccine antigens.

Clinical data from co-administration of ***Boostrix*** with a trivalent inactivated influenza vaccine in subjects aged between 19 and 64 years demonstrated that the immune responses to the tetanus, diphtheria, pertussis toxoid (PT) and influenza antigens were unaffected. Lower geometric mean concentrations (GMCs) were observed for the pertussis filamentous haemagglutinin (FHA) and pertactin (PRN) antigens; however, these data do not suggest clinically relevant interference. No differences were observed in a predefined exploratory cohort when the vaccines were given concomitantly or separately to subjects aged 65 years and older.

Clinical data from co-administration of ***Boostrix*** with MenACWY conjugate vaccines in subjects aged 9 to 25 years demonstrated that the immune responses to the tetanus, diphtheria and meningococcal antigens were unaffected. Lower GMCs were observed for the pertussis antigens; however, these data do not suggest clinically relevant interference.

Concomitant use with other inactivated vaccines and with immunoglobulin is unlikely to result in clinically relevant interference with the immune responses.

If ***Boostrix*** is to be given at the same time as another injectable vaccine or immunoglobulin, the products should always be administered at different sites.

As with other vaccines, patients receiving immunosuppressive therapy or patients with immunodeficiency may not achieve an adequate response. In these patients, when tetanus vaccine is needed for tetanus prone wound, plain tetanus vaccine will be used.

Pregnancy and Lactation

Fertility

No human data available. Animal studies do not indicate direct or indirect harmful effects with respect to female fertility.

Pregnancy

Boostrix can be used between 27 and 36 weeks of pregnancy in accordance with official recommendations.

For data relating to the prevention of pertussis disease in infants born to women vaccinated during pregnancy, see section *Pharmacodynamics*.

Safety data from a randomised controlled clinical trial (341 pregnancy outcomes) where ***Boostrix*** was administered to pregnant women between 27 and 36 weeks of pregnancy have shown no vaccine related adverse effect on pregnancy or on the health of the foetus/newborn child (see section *Adverse Reactions*).

Safety data from prospective clinical studies on the use of ***Boostrix*** or ***Boostrix Polio*** during the first and second trimester of pregnancy are not available.

Additional safety data obtained from a prospective observational study with ***Boostrix*** (793 pregnancy outcomes) and from post-marketing surveillance with ***Boostrix*** and ***Boostrix Polio***, where pregnant women were vaccinated during the third trimester in a period that partially overlaps with the weeks of pregnancy from the randomized controlled clinical trial (i.e. between 27 and 36 weeks), have shown no vaccine related adverse effect on pregnancy or on the health of the foetus/newborn child.

As with other inactivated vaccines, it is not expected that vaccination with ***Boostrix*** harms the foetus at any trimester of pregnancy.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or post-natal development.

Lactation

The safety of ***Boostrix*** when administered to breast-feeding women has not been evaluated.

It is unknown whether ***Boostrix*** is excreted in human breast milk.

Boostrix should only be used during breast-feeding when the possible advantages outweigh the potential risks.

Effects on Ability to Drive and Use Machines

The vaccine is unlikely to produce an effect on the ability to drive and use machines.

Adverse Reactions

Clinical Trial Data

The safety profile below is based on data from clinical trials where ***Boostrix*** was administered to 839 children (from 4 to 9 years of age) and 1,931 adults, adolescents and children (above 10 years of age).

Adverse reactions reported are listed according to the following frequency:

Very common	≥1/10
Common	≥1/100 and <1/10
Uncommon	≥1/1,000 and <1/100
Rare	≥1/10,000 and <1/1,000
Very rare	<1/10,000

Children from 4 to 9 years of age

Infections and infestations

Uncommon : upper respiratory tract infection

Metabolism and nutrition disorders

Common : anorexia

Psychiatric disorders

Very common : irritability

Nervous system disorders

Very common : somnolence
Common : headache
Uncommon : disturbances in attention

Eye disorders

Uncommon : conjunctivitis

Gastrointestinal disorders

Common : diarrhoea, vomiting, gastrointestinal disorders

Skin and subcutaneous tissue disorders

Uncommon : rash

General disorders and administration site conditions

Very common : injection site reactions (including pain, redness and swelling), fatigue
Common : fever ≥37.5°C (including fever >39°C)
Uncommon : other injection site reactions (such as induration), pain

Adults, adolescents and children from the age of 10 years onwards

Infections and infestations

Uncommon : upper respiratory tract infection, pharyngitis

Blood and lymphatic system disorders

Uncommon : lymphadenopathy

Nervous system disorders

Very common : headache
Common : dizziness
Uncommon : syncope

Respiratory, thoracic and mediastinal disorders

Uncommon : cough

Gastrointestinal disorders

Common : nausea, gastrointestinal disorders
Uncommon : diarrhoea, vomiting

Skin and subcutaneous tissue disorders

Uncommon : hyperhidrosis, pruritus, rash

Musculoskeletal and connective tissue disorders

Uncommon : arthralgia, myalgia, joint stiffness, musculoskeletal stiffness

General disorders and administration site conditions

Very common	: injection site reactions (including pain, redness and swelling), fatigue, malaise
Common	: fever ≥37.5°C, injection site reactions (such as injection site mass and injection site abscess sterile)
Uncommon	: fever >39°C, influenza-like illness, pain

Reactogenicity after repeat dose of ***Boostrix***
Data on 146 subjects suggest a small increase in local reactogenicity (pain, redness, swelling) with repeated vaccination according to a 0, 1, 6 months schedule in adults (>40 years of age).

Subjects fully primed with 4 doses of DTPw followed by a ***Boostrix*** dose around 10 years of age show an increase of local reactogenicity after an additional ***Boostrix*** dose administered 10 years later.

Safety in women vaccinated with dTpa during pregnancy
In a randomized controlled clinical trial where women were vaccinated between 27 and 36 weeks of pregnancy, the safety profile observed was similar in the dTpa-vaccinated group as compared to the control group. The types and rates of solicited/unsolicited adverse events are in line with the observations available for the general population.

The following adverse events of interest were reported during the randomized controlled clinical trial:

- No pregnancy/neonate-related adverse events of interest were considered related to ***Boostrix*** vaccination during the study.
- Pregnancy/neonate-related adverse events of interest were reported at similar rates (below 5%) in both study groups, the most common being premature labor (3.8% of women who received ***Boostrix*** vs 3.2% who received placebo during pregnancy) and premature rupture of membranes (3.8% of women who received ***Boostrix*** vs 4.3% who received placebo during pregnancy).
- There were no maternal or neonatal deaths.
- Congenital anomaly of infants born to vaccinated mothers was reported for 2.6% and 2.3% of women who received ***Boostrix*** vs those who received placebo during pregnancy, respectively. No safety concern was identified.

Post-Marketing Data
Blood and lymphatic system disorders
Rare : angioedema

Immune system disorders
Very rare : allergic reactions, including anaphylactic and anaphylactoid reactions

Nervous system disorders
Rare : convulsions (with or without fever)

Skin and subcutaneous tissue disorders
Rare : urticaria

General disorders and administration site conditions
Rare : extensive swelling of the vaccinated limb, asthenia

Adverse events should be reported to GSK Indonesia via website https://gsk.public.reportum.com and Pusat Farmakovigilans/MESO Nasional Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif Badan Pengawas Obat dan Makanan.
Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Phone: +62-21-4244691 Ext.1079
Website: https://e-meso.pom.go.id/ADR

Overdose
Cases of overdose have been reported during post-marketing surveillance. Adverse events following overdosage, when reported, were similar to those reported with normal vaccine administration.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamics
Pharmaco-therapeutic group: Bacterial vaccines combined, ATC code J07AJ52.

Immune response

Approximately one month following booster vaccination with ***Boostrix***:

- seropositivity/seroprotection rate against the different vaccine components was at least 99% in children from 4 to 9 years of age.
- seropositivity/seroprotection rate against the different vaccine components was at least 97% in adults and adolescents from 10 years of age.

Results of the comparative studies with commercial dT vaccines indicates that the degree and duration of protection would not be different from those obtained with these vaccines.

Efficacy in protecting against pertussis

There is currently no correlate of protection defined for pertussis; however, the protective efficacy of GlaxoSmithKline Biologicals' DTPa (***Infanrix***) vaccine against WHO-defined typical pertussis (≥21 days of paroxysmal cough with laboratory confirmation) was demonstrated in the following 3-dose primary studies:

- a prospective blinded household contact study performed in Germany (3, 4, 5 months schedule). Based on data collected from secondary contacts in households where there was an index case with typical pertussis, the protective efficacy of the vaccine was 88.7%. Protection against laboratory confirmed mild disease, defined as 14 days or more of cough of any type was 73% and 67% when defined as 7 days or more of cough of any type.
- an NIH sponsored efficacy study performed in Italy (2, 4, 6 months schedule). The vaccine efficacy was found to be 84%. When the definition of pertussis was expanded to include clinically milder cases with respect to type and duration of cough, the efficacy of ***Infanrix*** was calculated to be 71% against >7 days of any cough and 73% against >14 days of any cough.

Vaccinees receiving ***Boostrix*** achieved antipertussis antibody titres greater than those in the German household contact study where the protective efficacy was 88.7%.

Passive protection against pertussis in infants (below 3 months of age) born to mothers vaccinated during pregnancy

In a randomised, cross-over, placebo-controlled study, higher pertussis antibody concentrations were demonstrated at delivery in the cord blood of babies born to mothers vaccinated with ***Boostrix*** (N=291) versus placebo (N=292) between 27 and 36 weeks of pregnancy. The concentrations of antibodies against the pertussis antigens PT, FHA and PRN were respectively 8, 16 and 21 times higher in the cord blood of babies born to vaccinated mothers versus controls. These antibody titres may provide passive protection against pertussis, as shown by observational effectiveness studies.

Immunogenicity in infants and toddlers born to mothers vaccinated during pregnancy

In follow-up trials in the infants following primary vaccination (n=268) and subsequently following booster vaccination in the same toddlers (n=229) born to the vaccinated mothers, the clinical data did not show clinically relevant interference between maternal vaccination with ***Boostrix*** and the infant and toddler response to diphtheria, tetanus, hepatitis B, inactivated polio virus, *Haemophilus influenzae* type b or pneumococcal antigens. Although lower concentrations of antibodies against some pertussis antigens were observed post-primary and post-booster vaccination in infants born to vaccinated mothers (as compared to infants born to unvaccinated mothers), 92.1-98.1% of the subjects born to vaccinated mothers showed a booster response against all pertussis antigens. Current epidemiological data on pertussis disease do not suggest any clinical relevance of this immune interference.

Effectiveness in the protection against pertussis disease in infants born to women vaccinated during pregnancy

Boostrix or ***Boostrix Polio*** vaccine effectiveness (VE) was evaluated in three observational studies, in UK, Spain and Australia. The vaccine was used during the third trimester of pregnancy, in an interval that overlaps with the period between 27 and 36 weeks of pregnancy, to protect infants below 3 months of age against pertussis disease, as part of a maternal vaccination programme.

Details of each study design and results are provided in the table below.

VE against pertussis disease for infants below 3 months of age born to mothers vaccinated with ***Boostrix/Boostrix Polio*** during the third trimester of pregnancy, in an interval that overlaps with the period between 27 and 36 weeks of pregnancy:

Study location	Vaccine	Study design	Vaccination effectiveness
UK	***Boostrix Polio***	Retrospective, screening method	88% (95% CI: 79, 93)
Spain	***Boostrix***	Prospective, matched case-control	90.9% (95% CI: 56.6, 98.1)
Australia	***Boostrix***	Prospective, matched case-control	69% (95% CI: 13, 89)

CI: confidence interval

If maternal vaccination occurs within two weeks before delivery, vaccine effectiveness in the infant may be lower than the figures in the table.

Persistence of immune system
Five to 6 years following vaccination with ***Boostrix***, at least 94% of children from the age of 4 years onwards were seroprotected or seropositive against all vaccine components, except for the pertussis toxoid component (52% of subjects were seropositive against pertussis toxoid).

Ten years following vaccination with ***Boostrix***, at least 86% of adults were seroprotected or seropositive against all vaccine components.

In adolescents, the percentage of subjects who were seroprotected or seropositive was at least 82% against all vaccine components, except for the pertussis toxoid component (61% of subjects were seropositive against pertussis toxoid).

Immune response after a repeat dose of ***Boostrix***
The immunogenicity of ***Boostrix***, administered 10 years after a previous booster dose with reduced-antigen content diphtheria, tetanus and acellular pertussis vaccine(s) has been evaluated. One month post vaccination, >99% of subjects were seroprotected against diphtheria and tetanus and seropositive against pertussis.

Immune response in subjects without prior or with unknown vaccination history
In adolescents aged from 11 to 18 years, without previous pertussis vaccination and no vaccination against diphtheria and tetanus in the previous 5 years, one dose of ***Boostrix*** induced an antibody response against pertussis and all subjects were protected against tetanus and diphtheria.

In subjects ≥40 years of age that had not received any diphtheria or tetanus containing vaccine in the past 20 years (including those who have never been vaccinated or whose vaccination status was unknown), one dose of ***Boostrix*** induced an antibody response against pertussis and protected against tetanus and diphtheria in the majority of cases.

Immune response and safety profile in subjects on active treatment for obstructive airway diseases
The safety and immunogenicity of ***Boostrix*** have been evaluated in a descriptive meta-analysis study combining data from 222 subjects ≥18 years of age vaccinated with ***Boostrix*** while on active treatment for obstructive airway disease such as asthma or Chronic Obstructive Pulmonary Disease (COPD). One month after ***Boostrix*** vaccination, the immune responses against diphtheria and tetanus antigens in terms of seroprotective rates (≥0.1 IU/mL) were respectively 89.0% and 97.2% and against pertussis in terms of booster responses these were 78.3%, 96.1% and 92.2% against pertussis toxoid (PT), filamentous haemagglutinin (FHA) and pertactin (PRN), respectively. These results are consistent with the responses obtained in the general adult population and with a similar safety profile.

Non-Clinical Information
Animal toxicology and/or pharmacology
Non-clinical data reveal no special hazard for humans based on conventional studies of safety and of toxicity.

PHARMACEUTICAL INFORMATION
List of Excipients
Sodium chloride, water for injections.

Shelf Life
The expiry date is indicated on the packaging.

Storage
Store in a refrigerator (2°C – 8°C).

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

Stability data indicate that the vaccine is stable at temperatures up to 37°C for 7 days. These data are intended to guide healthcare professionals in case of temporary temperature excursion only.

Protect from light.

The storage conditions are detailed on the packaging.

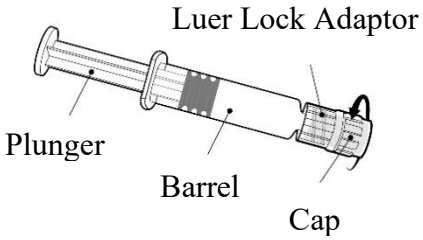
Nature and Contents of Container
0.5 mL of suspension in a pre-filled syringe (type I glass) with a plunger stopper (butyl rubber) and with a rubber tip cap.

The tip cap and rubber plunger stopper of the pre-filled syringe are not made with natural rubber latex.

Incompatibilities
Boostrix should not be mixed with other vaccines in the same syringe.

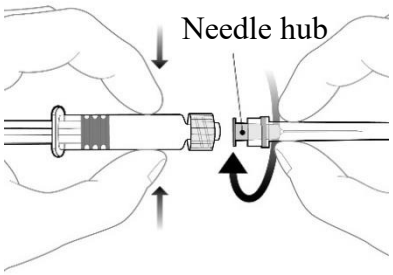
Use and Handling
Prior to vaccination, the vaccine should be well shaken in order to obtain a homogeneous turbid white suspension and visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, do not administer the vaccine.

Instruction for the pre-filled syringe



Hold the syringe by the barrel, not by the plunger.

Unscrew the syringe cap by twisting it anticlockwise.



To attach the needle, connect the hub to the Luer Lock Adaptor and rotate a quarter turn clockwise until you feel it lock.

Do not pull the syringe plunger out of the barrel. If it happens, do not administer the vaccine.

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

HARUS DENGAN RESEP DOKTER

Box, 1 pre-filled syringe @ 0.5 mL Reg. No. DKI2176703143A1

Imported by
PT Glaxo Wellcome Indonesia
Jakarta, Indonesia

Manufactured by
GlaxoSmithKline Biologicals, s.a.
Rixensart, Belgium

Version number: 02
Reference: GDS16/IPI17 + Needle free
Date of local revision: 4 March 2026

BROSUR KEMASAN: INFORMASI UNTUK PASIEN

Boostrix, suspensi untuk injeksi

Diphtheria, tetanus, pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content)

Baca Brosur Ini Dengan Saksama Sebelum Anda atau Anak Anda Mendapatkan Vaksin Ini.
- Simpan brosur ini. Anda mungkin membutuhkan untuk membacanya lagi.
- Jika Anda memiliki pertanyaan lebih lanjut, Anda dapat menghubungi dokter atau apoteker Anda.
- Vaksin ini diresepkan untuk Anda atau anak Anda. Jangan diberikan untuk orang lain.
- Jika ada kejadian ikutan pasca imunisasi (KIPI) yang menjadi serius atau jika Anda memperhatikan terdapat KIPI yang tidak terdapat pada brosur ini, harap hubungi dokter atau apoteker Anda.

Pada Brosur Ini:

1. Apakah *Boostrix* Itu dan Digunakan untuk Apa

Boostrix adalah vaksin yang digunakan untuk melindungi Anda atau anak Anda dari 3 penyakit:
- **Difteri**: infeksi bakteri serius yang terutama mempengaruhi saluran napas dan terkadang kulit. Saluran napas menjadi bengkak menyebabkan masalah pernapasan serius dan terkadang kesulitan bernapas. Bakteri ini juga mengeluarkan racun. Racun ini dapat menyebabkan kerusakan saraf, masalah jantung, dan bahkan kematian.
- **Tetanus (*Lockjaw*)**: bakteri tetanus masuk ke dalam tubuh melalui sayatan, goresan atau luka di kulit. Luka yang lebih mungkin terkena infeksi tetanus adalah luka bakar, patah tulang, luka yang dalam atau luka yang terkontaminasi dengan tanah, debu, kotoran kuda atau serpihan kayu. Bakteri ini mengeluarkan racun. Racun ini dapat menyebabkan kekakuan otot, spasme/ tegang otot yang menyakitkan, kejang dan bahkan kematian. Spasme/ tegang otot dapat terjadi cukup kuat sehingga dapat menyebabkan patah tulang belakang.
- **Pertusis (batuk rejan)**: penyakit sangat menular yang mempengaruhi saluran napas. Penyakit ini menyebabkan batuk berat yang dapat menimbulkan masalah pada pernapasan. Batuk sering menghasilkan bunyi "*whooping*". Batuk dapat berlangsung selama satu hingga dua bulan atau lebih. Batuk rejan juga dapat menyebabkan infeksi telinga, infeksi saluran napas (bronkitis) yang dapat berlangsung lama, infeksi paru (pneumonia), kejang, kerusakan otak dan bahkan kematian.

Bagaimana Vaksin Bekerja
- ***Boostrix*** membantu tubuh Anda atau anak Anda untuk membuat perlindungannya sendiri (antibodi). Antibodi ini akan melindungi Anda dan anak Anda dari penyakit tersebut.
- Penggunaan ***Boostrix*** selama kehamilan akan membantu melindungi bayi Anda dari batuk rejan dalam beberapa bulan pertama kehidupan sebelum bayi Anda mendapatkan imunisasi primer.
- Seperti semua vaksin lainnya, ***Boostrix*** mungkin tidak sepenuhnya melindungi semua anak atau orang yang divaksinasi.
- ***Boostrix*** hanya akan melindungi dari infeksi yang disebabkan oleh patogen yang telah dikembangkan dalam vaksin ini.

2. Sebelum Anda atau Anak Anda Mendapatkan *Boostrix*

***Boostrix* tidak boleh diberikan:**
- Jika Anda atau anak Anda alergi (hipersensitif) terhadap ***Boostrix*** atau bahan apa pun yang terkandung dalam ***Boostrix***. Zat aktif dan bahan lainnya yang terkandung dalam ***Boostrix*** tercantum dalam *Bagian 5* dari brosur. Tanda-tanda reaksi alergi mungkin termasuk ruam pada kulit yang disertai gatal, sesak napas dan pembengkakan pada wajah atau lidah.
- Jika Anda atau anak Anda sebelumnya memiliki reaksi alergi terhadap vaksin difteri, tetanus, atau pertusis (batuk rejan).
- Jika Anda atau anak Anda mengalami gangguan sistem saraf (ensefalopati) dalam waktu 7 hari setelah vaksinasi sebelumnya dengan vaksin pertusis (batuk rejan).

- Jika Anda atau anak Anda mengalami penurunan trombosit sementara (yang meningkatkan risiko perdarahan atau memar) atau gangguan pada otak atau saraf setelah vaksinasi sebelumnya dengan vaksin difteri dan/ atau tetanus.

Konsultasikan dengan dokter Anda segera jika Anda atau anak Anda mengalami salah satu dari tanda tersebut di atas.

Kondisi yang perlu diwaspadai saat penggunaan *Boostrix*:
- Jika Anda atau anak Anda mengalami infeksi berat disertai demam tinggi. Pada kasus ini, vaksinasi akan ditunda hingga kondisi membaik. Infeksi ringan seperti pilek seharusnya tidak menjadi masalah, tetapi konsultasikan dengan dokter Anda terlebih dahulu.
- Jika setelah sebelumnya mendapatkan ***Boostrix*** atau vaksin pertusis (batuk rejan) lainnya, Anda atau anak Anda mengalami hal berikut, khususnya:
  - Demam tinggi (lebih dari 40°C) dalam waktu 48 jam setelah vaksinasi.
  - Kondisi pingsan atau kondisi mirip-syok dalam waktu 48 jam setelah vaksinasi.
  - Menangis terus-menerus selama 3 jam atau lebih dalam waktu 48 jam setelah vaksinasi.
  - Kejang dengan atau tanpa demam tinggi dalam waktu 3 hari setelah vaksinasi.
- Jika Anda atau anak Anda mengalami gangguan neurologis, termasuk kejang infantil, epilepsi yang tidak terkontrol, atau ensefalopati progresif (penyakit otak).
- Jika Anda atau anak Anda memiliki gangguan pendarahan atau mudah memar.
- Jika Anda atau anak Anda memiliki kecenderungan untuk kejang karena demam, atau jika ada riwayat kejang dalam keluarga.

Anak-anak atau orang dengan sistem kekebalan yang lemah, misalnya karena infeksi HIV atau karena obat-obatan yang menekan sistem kekebalan, mungkin tidak mendapatkan manfaat penuh dari ***Boostrix***.

Pingsan atau periode ketidaksadaran atau kurangnya kewaspadaan, kejang telah terjadi pada anak-anak yang diberikan vaksin lain yang mengandung satu atau lebih zat aktif dari ***Boostrix***. Kondisi tersebut biasanya terjadi dalam waktu dua hingga tiga hari setelah vaksinasi.

Pingsan dapat terjadi setelah, atau bahkan sebelum suntikan jarum, oleh karena itu beri tahu dokter atau perawat jika Anda atau anak Anda mempunyai riwayat pingsan pada penyuntikan sebelumnya.

Penggunaan obat dan vaksin lain
- Konsultasikan kepada dokter Anda jika Anda atau anak Anda sedang atau baru saja menggunakan obat lain, termasuk obat-obatan yang diperoleh tanpa resep atau baru saja mendapatkan vaksin lain.
- ***Boostrix*** dapat diberikan bersamaan dengan beberapa vaksin lain: *unadjuvanted inactivated seasonal influenza vaccines*, *human papilloma virus vaccines*, *meningococcal serogroups* A, C, W-135 *and* Y (MenACWY) *conjugate vaccines*. Tempat suntikan yang berbeda akan digunakan untuk setiap jenis vaksin.

Kehamilan dan menyusui
- Jika Anda sedang hamil, merasa mungkin sedang hamil atau berencana untuk memiliki anak, dokter Anda akan membantu Anda untuk memutuskan apakah Anda sebaiknya mendapatkan ***Boostrix***.
- Dokter Anda akan memberi tahu Anda kemungkinan risiko dan manfaat dari vaksinasi ***Boostrix*** selama menyusui.
- Konsultasikan dengan dokter atau apoteker Anda sebelum menggunakan obat/ vaksin apa pun.

Berkendara dan menjalankan mesin
Boostrix cenderung tidak mempengaruhi kemampuan Anda mengemudi atau menjalankan mesin. Bagaimanapun juga, jangan mengemudi atau menjalankan mesin jika Anda merasa tidak enak badan.

3. Bagaimana Cara Pemberian *Boostrix*

- Anda atau anak Anda akan mendapatkan suntikan tunggal pada tanggal yang telah dijadwalkan.

- ***Boostrix*** akan diberikan berupa suntikan ke dalam otot dan tidak boleh diberikan melalui pembuluh darah vena.
- ***Boostrix*** dapat digunakan jika Anda atau anak Anda memiliki risiko terkena tetanus karena luka.
- Dokter Anda akan memeriksa apakah Anda atau anak Anda sebelumnya telah mendapatkan vaksin difteri, tetanus dan/ atau pertusis.
- Vaksinasi ulang untuk difteri, tetanus, dan pertusis mungkin dilakukan sesuai dengan rekomendasi resmi. Dokter Anda akan memberitahu Anda.

4. Kemungkinan Kejadian Ikutan Pasca Imunisasi (KIPI)

Seperti semua obat/ vaksin, ***Boostrix*** dapat menyebabkan KIPI, meskipun tidak semua orang mengalaminya.

Seperti halnya semua vaksin injeksi, reaksi alergi berat (reaksi anafilaksis dan anafilaktoid) mungkin sangat jarang terjadi (hingga 1 dari 10.000 dosis vaksin). Hal ini dapat dikenali dengan:
- Ruam disertai gatal pada tangan dan kaki,
- Pembengkakan mata dan wajah,
- Kesulitan bernapas atau menelan,
- Penurunan tekanan darah secara tiba-tiba dan kehilangan kesadaran.

Reaksi ini biasanya akan terjadi sebelum meninggalkan rumah sakit/ruang praktik dokter. Bagaimanapun juga, apabila Anda atau anak Anda mengalami gejala-gejala ini, Anda harus segera menghubungi dokter.

KIPI yang terjadi pada anak-anak dari usia 4 sampai 9 tahun

Sangat umum (ini dapat terjadi dengan lebih dari 1 dalam 10 dosis vaksin):
- Rewel
- Mengantuk
- Bengkak, nyeri, kemerahan pada tempat penyuntikan
- Kelelahan

Umum (ini dapat terjadi hingga 1 dari 10 dosis vaksin):
- Kehilangan selera makan
- Sakit kepala
- Muntah dan diare
- Demam (lebih dari 37,5°C)

Tidak umum (ini dapat terjadi hingga 1 dari 100 dosis vaksin):
- Infeksi saluran pernapasan atas
- Gangguan perhatian
- Kotoran pada mata disertai gatal dan kerak pada kelopak mata (konjungtivitis)
- Ruam kulit
- Nyeri
- Benjolan keras pada tempat penyuntikan

KIPI yang terjadi pada dewasa, remaja, dan anak-anak dari usia 10 tahun ke atas

Sangat umum (ini dapat terjadi dengan lebih dari 1 dalam 10 dosis vaksin):
- Sakit kepala
- Bengkak, nyeri, kemerahan pada tempat penyuntikan
- Kelelahan
- Merasa tidak enak badan

Umum (ini dapat terjadi hingga 1 dari 10 dosis vaksin):
- Pusing
- Mual
- Demam (lebih dari 37,5°C)
- Benjolan keras dan abses pada tempat penyuntikan

Tidak umum (ini dapat terjadi hingga 1 dari 100 dosis vaksin):
- Infeksi saluran pernapasan atas
- Sakit tenggorokan dan rasa tidak nyaman saat menelan (faringitis)
- Pembengkakan kelenjar di leher, ketiak, atau lipat paha (limfadenopati)

- Pingsan
- Batuk
- Diare
- Muntah
- Keringat berlebih (*hyperhidrosis*)
- Gatal
- Ruam kulit
- Kekakuan sendi
- Nyeri sendi (*arthralgia)*
- Nyeri otot (*myalgia*)
- Demam (lebih dari 39°C)
- Gejala mirip flu, seperti demam, sakit tenggorokan, hidung berair, batuk, dan menggigil
- Nyeri

KIPI berikut tidak spesifik untuk sejumlah kelompok umur
Jarang (ini dapat terjadi hingga 1 dari 1.000 dosis vaksin):
- Pembengkakan pada wajah, bibir, mulut, lidah atau tenggorokan yang dapat menyebabkan kesulitan menelan atau bernapas (*angioedema*)
- Kejang (dengan atau tanpa demam)
- Gatal-gatal (*urticaria*)
- Pembengkakan besar pada tungkai atau lengan yang divaksinasi
- Kelemahan yang tidak biasa (*asthenia*)

Keamanan pada wanita yang divaksinasi dTpa selama kehamilan
KIPI berikut dilaporkan berdasarkan data keamanan dari hasil studi klinis terkontrol secara acak (*randomized controlled clinical trial*) pada wanita yang divaksinasi dTpa selama kehamilan:
- Persalinan prematur (3,8% wanita yang menerima ***Boostrix*** vs 3,2% wanita yang menerima plasebo* selama kehamilan).
- Ketuban pecah dini (3,8% wanita yang menerima ***Boostrix*** vs 4,3% wanita yang menerima plasebo* selama kehamilan).
- Kelainan bawaan pada bayi yang lahir dari ibu yang divaksinasi (2,6% wanita yang menerima ***Boostrix*** vs 2,3% wanita yang menerima plasebo* selama kehamilan).
- Tidak teridentifikasi adanya masalah keamanan.

Pada penelitian yang sama dilaporkan bahwa tidak terdapat kematian pada ibu hamil dan neonatus**.

*Plasebo adalah obat yang tidak mengandung zat aktif yang sering digunakan sebagai pembanding untuk menguji efektivitas suatu obat dalam uji klinis.
**Neonatus adalah bayi yang baru lahir 28 hari pertama kehidupan.

Apabila Anda mengalami KIPI
Jika KIPI menjadi serius, atau jika Anda melihat terdapat KIPI yang tidak tercantum dalam brosur ini, segera konsultasikan pada dokter atau apoteker Anda.

Laporkan Kejadian Tidak Diinginkan (KTD) ke GSK Indonesia melalui situs web https://gsk.public.reportum.com

5. Informasi Lain

Apa kandungan *Boostrix*
1 dosis (0,5 mL) mengandung:

Zat aktif:	
Diphtheria toxoid[1]	*not less than 2 International Units (IU) (2.5 Lf)*
Tetanus toxoid[1]	*not less than 20 International Units (IU) (5 Lf)*
Bordetella pertussis *antigens*	
Pertussis toxoid[1]	*8 micrograms*
Filamentous haemagglutinin[1]	*8 micrograms*
Pertactin[1]	*2.5 micrograms*
[1] *adsorbed on aluminium hydroxide, hydrated ($Al(OH)_3$) and aluminium phosphate ($AlPO_4$)*	*0.3 milligrams Al^{3+}* *0.2 milligrams Al^{3+}*

Bahan lain dalam ***Boostrix***:
Sodium chloride dan *water for injections*.

Bagaimana bentuk dari *Boostrix* dan isi kemasan
Boostrix berupa suspensi putih keruh yang tersimpan dalam *pre-filled syringe* (0,5 mL). Setelah penyimpanan, endapan putih dan supernatan bening akan terlihat.

HARUS DENGAN RESEP DOKTER

Diproduksi oleh:
GlaxoSmithKline Biologicals s.a
Rixensart, Belgium

Diimpor oleh:
PT Glaxo Wellcome Indonesia
Jakarta, Indonesia

Dus, 1 *pre-filled syringe* @ 0,5 mL Reg. No. DKI2176703143A1

Version number: 02
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