boostrix™

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 (AlPO4) 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.

PHARMACEUTICAL FORM

Suspension for injection.

Indications

Boostrix™ is indicated for booster vaccination against diphtheria, tetanus and pertussis of individuals from the age of four years onwards.

Dosage and Administration

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™ may be administered to adolescents and adults with unknown vaccination status or incomplete vaccination against diphtheria, tetanus and pertussis as part of an immunisation series against diphtheria, tetanus and pertussis . 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 .

Contraindications

Boostrix™ should not be administered to subjects with known hypersensitivity to any component of the vaccine, or to subjects having shown signs of hypersensitivity after previous administration of diphtheria, tetanus or pertussis vaccines.

Boostrix™ is contra-indicated 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 immunisation against diphtheria and/or tetanus .

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. 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 (hypotonichyporesponsiveness 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

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

When considered necessary, ***Boostrix™*** can be administered simultaneously with other vaccines or immunoglobulins.

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

Safety data from a prospective observational study where ***Boostrix™*** was administered to pregnant women during the third trimester (793 pregnancy outcomes) as well as data from post-marketing surveillance where pregnant women were exposed to Boostrix™ or to ***Boostrix™ Polio*** (dTpa-IPV vaccine) have shown no vaccine related adverse effect on pregnancy or on the health of the foetus/newborn child.

The use of ***Boostrix™*** may be considered during the third trimester of pregnancy.

Human data from prospective clinical studies on the use of Boostrix™ during the first and second trimester of pregnancy are not available.

Limited data indicate that maternal antibodies may reduce the magnitude of the immune response to some vaccines in infants born from mothers vaccinated with Boostrix™ during pregnancy. The clinical relevance of this observation is unknown.

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

Boostrix™ should only be used during pregnancy when the possible advantages outweigh the possible risks for the foetus.

Adverse Reactions

Children from 4 to 9 years of age

Uncommon: upper respiratory tract infection, disturbances in attention, conjunctivitis, rash, other injection site reactions (such as induration), pain

Common: fever ≥ 37.5 °C (including fever > 39 °C), anorexia, headache, diarrhoea, vomiting, gastrointestinal disorders

Very common: injection site reactions (including pain, redness and swelling),fatigue, irritability, somnolence

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

Uncommon: upper respiratory tract infection, pharyngitis Blood and lymphatic system disorders, lymphadenopathy, fever > 39 °C, influenza like illness, pain.

Very common: headache, 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), dizziness, nausea, gastrointestinal disorders

Uncommon: syncope, cough, diarrhoea, vomiting, hyperhidrosis, pruritus, rash, arthralgia, myalgia, joint stiffness, musculoskeletal stiffness

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.

Post Marketing Data

Rare: angioedema, fever > 39 °C, influenza like illness, pain, urticaria, extensive swelling of the vaccinated limb, asthenia

Very rare: allergic reactions, including anaphylactic and anaphylactoid reactions

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.

Incompatibilities

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

Special Precautions for Storage

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.

Instructions for Use/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, discard the vaccine.

The vaccine should be administered immediately after opening the container (not later than 8 hours after opening).

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

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