Immune system disorders
Allergic reactions, including anaphylactic and anaphylactoid reactions

Nervous system disorders
Collapse or shock-like state (hypotonic-hyporesponsiveness episode), convulsions (with or without fever) within 2 to 3 days of vaccination

Respiratory, thoracic and mediastinal disorders
Apnoea [see section 4.4 for apnoea in very premature infants (≤ 28 weeks of gestation)]

Skin and subcutaneous tissue disorders
Angioneurotic oedema

General disorders and administration site conditions
Swelling of the entire injected limb[3]

[1]reported only with booster vaccination
[2]very common for booster vaccination
[3]Children primed with acellular pertussis vaccines are more likely to experience swelling reactions after booster administration in comparison with children primed with whole cell vaccines. Local swelling at the injection site (>50 mm) and diffuse swelling may be more frequent (very common and common, respectively) when the booster dose is administered between 4 and 6 years. These reactions resolve over an average of 4 days.
[4]reported with D and T vaccines

4.9 Overdose
Cases of overdose have been reported during post-marketing surveillance. Adverse events, when reported, are not specific but similar to adverse events reported with normal vaccine administration.

5. Pharmacological particulars

5.1. Pharmacodynamic properties.
Pharmaco-therapeutic group: Bacterial vaccines, ATC code J07AJ52.

Immune response of Infanrix primary immunisation:
One month after a three-dose primary vaccination course in the first 6 months of life more than 99% of infants vaccinated with Infanrix™ had antibody titers of more than 0.1 IU/ml to both diphtheria and tetanus.
The vaccine contains PT, FHA and pertactin, antigens which are considered to play an important role in protection against pertussis disease. In clinical studies, the vaccine response to these pertussis antigens was more than 95%.

Immune response of Infanrix™ booster immunisation:
Following administration of an Infanrix™ booster in the second year of life (13-24 months) all Infanrix™ primed infants had antibody titers of more than 0.1 IU/ml to both diphtheria and tetanus. The booster response to the pertussis antigens was seen in more than 96% of these children.

Protective efficacy of Infanrix™:
The protective efficacy of Infanrix™ against WHO-defined typical pertussis (≥ 21 days of paroxysmal cough with laboratory confirmation) was demonstrated in :
- 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.

5.2 Pharmacokinetic properties
Evaluation of pharmacokinetic properties is not required for vaccines.

5.3 Preclinical safety data
Appropriate safety tests have been performed.

6. Pharmaceutical particulars

6.1List of excipients
Aluminium hydroxide, sodium chloride, water for injections. Formaldehyde and Polysorbate 80 are present as residuals from the manufacturing process.

6.2 Incompatibilities
Infanrix™ should not be mixed with other vaccines in the same syringe, with the exception of Hiberix™ or other PRP-T Hib vaccines.

6.3 Shelf life
The expiry date of the vaccine is indicated on the label and packaging.

6.4 Special precautions for storage
Infanrix™ should be stored at +2°C to +8°C.
Do not freeze. Discard if the vaccine has been frozen.

6.5 Nature and contents of container
Infanrix™ is presented as a turbid white suspension in a glass vial or glass prefilled syringe. Upon storage a white deposit and clear supernatant is observed.
The vials and prefilled syringes are made of neutral glass type I, which conforms to European Pharmacopoeia Requirements.

6.6 Instructions for use, handling and disposal (if appropriate)
How to use Infanrix™
Infanrix™ is presented as a turbid white suspension. Upon storage, a white deposit and clear supernatant is observed. 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.
To mix Infanrix™ and Hiberix™
Infanrix™ may be used to reconstitute Hiberix™ vaccine for simultaneous administration via one injection. Hiberix™ is presented as a white Hib pellet in a vial, with a clear and colourless sterile diluent (saline) in either a second vial or a prefilled syringe. Discard the diluent.
The combined DTPa-Hib vaccine must be reconstituted by adding the entire contents of a monodose Infanrix™ prefilled syringe to the monodose vial containing the white Hiberix™ pellet. After the addition of Infanrix™ to the Hiberix™ pellet, the mixture should be well shaken until the Hiberix™ pellet is completely dissolved in the Infanrix™ suspension.
The reconstituted combined vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to administration. In the event of either being observed, discard the reconstituted vaccine.
A new needle should be used to administer the vaccine. After reconstitution, the vaccine should be injected promptly.

For further information, refer to manufacturer.

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gsk GlaxoSmithKline