

Prescribing information – See Summary of Product Characteristics before prescribing

Boostrix-IPV Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content). **Composition:** 0.5ml dose contains suspension of diphtheria toxoid ≥ 21 U, tetanus toxoid ≥ 20 U, *Bordetella pertussis* antigens (Pertussis toxoid 8 μ g, Filamentous Haemagglutinin 8 μ g, Pertactin 2.5 μ g), 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). **Uses:** Booster vaccination against diphtheria, tetanus, pertussis, and poliomyelitis diseases in individuals from 3 years of age. **Dosage and administration:** Administration should be based on official recommendations. A single 0.5ml dose by deep intramuscular (IM) injection, preferably in the deltoid region. **Side effects:** See SPC for full list and details. **Age 4-8 years:** *Very common:* somnolence; injection site reactions and pain. *Common:* anorexia; irritability; headache; pyrexia. **Age 10-93 years:** *very common:* headache; injection site reactions and pain; fatigue; malaise. *Common:* gastrointestinal disorders; pyrexia. **Serious side effects** (post-marketing surveillance): allergic reactions including anaphylactic and anaphylactoid reactions; hypotonic-hyporesponsiveness episode; convulsions; angioedema; rare adverse reactions on the central or peripheral nervous system after tetanus toxoid containing vaccines. **Contraindications:** Hypersensitivity to any component of the vaccine or to neomycin or polymyxin. Hypersensitivity following previous administration of diphtheria,

tetanus, pertussis or polio vaccines; encephalopathy of unknown aetiology ≤ 7 days after previous pertussis vaccination; transient thrombocytopenia or neurological complications after previous diphtheria and/or tetanus vaccination. **Precautions:** Appropriate medical treatment and supervision should be available in case of anaphylactic shock. Vaccination should be preceded by review of medical history. Careful consideration is required with previous temporal association of adverse events after a pertussis containing vaccine. The risk-benefit of immunising or deferring vaccination should be carefully weighed in case of new onset or progression of neurological disorder. Administer with caution in cases of thrombocytopenia or bleeding disorder. Do not administer intravascularly. See SPC for full details. **Legal category:** POM. **MA number:** PL 10592/0214. **Presentation and basic NHS cost:** 0.5ml suspension in pre-filled syringe (Type I glass) with stopper (rubber butyl) with or without needles. Pack size of 1, NHS Cost £22.74. **MA holder:** SmithKline Beecham Ltd, 980 Great West Road, Brentford, Middlesex, TW8 9GS. Trading as GlaxoSmithKline UK, Stockley Park West, Uxbridge, Middlesex, UB11 1BT. **Further information available from:** *Customer Contact Centre, GlaxoSmithKline, Stockley Park West, Uxbridge, Middlesex UB11 1BT; customercontactuk@gsk.com; Freephone: 0800 221 441. Date of preparation:* January 2019 UK/BOO/0001/19.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard, or search for MHRA yellow card in the Google Play or Apple App store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.