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 ≥21IU, tetanus toxoid ≥20IU, Bordetella pertussis antigens (Pertussis toxoid 8μg, Filamentous Haemagglutinin 8μg, Pertactin 2.5μg), 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. Prior to use, the vaccine should be at room temperature, and well shaken in order to obtain a homogeneous turbid white suspension. 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. 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. See SPC for full details. 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.

Pregnancy: The use of Boostrix-IPV may be considered during the third trimester of pregnancy. For data relating to the prevention of pertussis disease in infants born to women vaccinated during pregnancy, see SPC. Safety data from a prospective observational study where Boostrix (dTpa component of Boostrix-IPV) was administered to pregnant women during the third trimester (793 pregnancy outcomes) as well as data from passive surveillance where pregnant women were exposed to Boostrix-IPV or to Boostrix in the 3rd and 2nd trimester have shown no vaccine related adverse effect on pregnancy or on the health of the foetus/newborn child. Human data from prospective clinical studies on the use of Boostrix-IPV during the first and second trimester of pregnancy are not available. However, as with other inactivated vaccines, it is not expected that vaccination with Boostrix-IPV harms the foetus at any trimester of pregnancy. The benefits versus the risks of administering Boostrix-IPV during pregnancy should be carefully evaluated. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or post-natal development (see SPC). 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. Breastfeeding: The effect of administration of Boostrix-IPV during lactation has not been assessed. Nevertheless, as Boostrix-IPV contains toxoids or inactivated antigens, no risk to the breastfed infant should be expected. The benefits versus the risk of administering Boostrix-IPV to breastfeeding women should carefully be evaluated by the health-care providers. 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. Code: PI-0502 (v2.0). Date of preparation: March 2019.

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.