

Prescribing information - Please consult the Summary of Product Characteristics (SPC) before prescribing.

Boostrix-IPV Diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content). **Composition:** 0.5 ml dose contains suspension of diphtheria toxoid ≥ 2 IU, tetanus toxoid ≥ 20 IU, *Bordetella pertussis* antigens (Pertussis toxoid 8 μg , Filamentous Haemagglutinin 8 μg , Pertactin 2.5 μg), 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). Excipients: para-aminobenzoic acid <0.07 nanograms, phenylalanine 0.0298 micrograms, <1mmol sodium and < 1mmol potassium per dose. **Indications:** Booster vaccination against diphtheria, tetanus, pertussis, and poliomyelitis diseases in individuals from 3 years of age; passive protection against pertussis in early infancy following maternal immunisation during pregnancy. **Dosage and administration:** Administration should be based on official recommendations. A single 0.5 ml 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. **Contraindications:** Hypersensitivity to any component of the vaccine or to formaldehyde, neomycin or polymyxin which are used in the manufacturing process. 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. Postpone in case of severe febrile illness. See SPC for full details. **Special warnings and precautions:** See SPC for full list. Always review medical history. Careful consideration required with previous temporal association of adverse events after a pertussis containing vaccine. Risk-benefit of immunising or deferring vaccination should be carefully weighed in case of new onset or progression of neurological disorder. Appropriate medical treatment and supervision should be available in case of anaphylactic shock. May administer subcutaneously with caution, according to official recommendations, in cases of thrombocytopenia or bleeding disorders. Do not administer intravascularly. Expected immune response may not be obtained in immunosuppressed patients. Syncope can occur. Para-aminobenzoic acid may cause allergic reactions. Phenylalanine may be harmful in patients with phenylketonuria. Record

product name and batch number. **Interactions:** For information on interactions and concomitant vaccination, please refer to the SPC. **Pregnancy and breastfeeding:** Boostrix-IPV can be used during the second/third trimester of pregnancy in accordance with official recommendations. For data on disease prevention in infants born to women vaccinated during pregnancy, see SPC. Data from a randomised controlled clinical trial (341 pregnancy outcomes) and from a prospective observational study (793 pregnancy outcomes) where Boostrix (dTpa component of Boostrix-IPV) was administered in third trimester found no adverse effect on pregnancy or foetus/newborn. No safety data from prospective clinical studies during the first/second trimester available. Passive surveillance of vaccination in third/second trimester found no adverse effect on pregnancy or foetus/newborn. As with other inactivated vaccines, it is not expected that vaccination with Boostrix-IPV harms the foetus at any trimester. Animal studies do not indicate direct or indirect harmful effects in pregnancy, embryonal/foetal development, parturition or post-natal development. Effect of administration during lactation has not been assessed. As Boostrix-IPV contains toxoids or inactivated antigens, no risk to the breastfed infant expected. The benefits versus the risk should carefully be evaluated. **Adverse reactions:** See SPC for full list and details. Age 4-8 years: *Very common* ($\geq 1/10$): somnolence; injection site reactions and pain. *Common* ($\geq 1/100$ to $< 1/10$): anorexia; irritability; headache; pyrexia, extensive swelling of vaccinated limb. 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. **Legal category:** POM. **MA number:** PL 10592/0214. **Presentation and basic NHS cost:** 0.5 ml 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. **Further information:** available from the GSK Customer Contact Centre, customercontactuk@gsk.com; Freephone: 0800 221 441. **Ref:** PI-7046 (V4). **Date of preparation:** July 2022.

Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk>, 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.