For further details concerning the contra-indications and precautions to be observed for pertussis-containing vaccines, see p.2230.

1. Hoffman HJ, *et al.* Diphtheria-tetanus-pertussis immunization and sudden infant death: results of the National Institute of Child Health and Human Development Cooperative Epidemiological Study of Sudden Infant Death Syndrome Risk Factors. *Pediatrics* 1987; **79:** 598–611.
2. Griffin MR, *et al.* Risk of sudden infant death syndrome after immunization with the diphtheria-tetanus-pertussis vaccine. *N Engl J Med* 1988; **319:** 618–23.
3. Mitchell EA, *et al.* Immunisation and the sudden infant death syndrome. *Arch Dis Child* 1995; **73:** 498–501.

Interactions

As for vaccines in general, p.2202.

For a report of a diminished immune response to *Haemophilus influenzae* conjugated vaccine when mixed with diphtheria, tetanus, and acellular pertussis vaccine, see Haemophilus Influenzae Vaccines, p.2213.

Uses and Administration

Combined diphtheria, tetanus, and pertussis vaccines are used for active immunisation of children. For discussion of immunisation schedules, see under Vaccines, p.2202.

Combined adsorbed vaccines may be given by deep subcutaneous or intramuscular injection (vaccines with acellular pertussis components are for intramuscular injection only) in usual doses of 0.5 mL. In the USA, a vaccine with an acellular pertussis component is used as part of the recommended schedule for primary immunisation. Three doses are given at intervals of 2 months (the first preferably at 2 months of age), a fourth dose at least 6 months after the third, and a fifth dose at school entry. Another dose of a vaccine specially formulated for use in adults and adolescents is given at 11 to 12 years of age.

Vaccines containing an acellular pertussis component are now preferred to those containing a whole-cell component (see Vaccine Development, p.2231). The non-adsorbed type of combined diphtheria, tetanus, and pertussis vaccines have weaker immunogenic properties than adsorbed vaccines and are no longer recommended.

Preparations

Ph. Eur.: Diphtheria, Tetanus and Pertussis (Acellular, Component) Vaccine (Adsorbed); Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed).

Proprietary Preparations (details are given in Part 3)
Arg.: Bustrix; Triacel; Vacuna Triple; ***Austral.:*** Boostrix; Infanrix; Tripacel; ***Austria:*** Boostrix; Infanrix; ***Belg.:*** Boostrix; Infanrix†; Triamer†; ***Braz.:*** DT-Coq/DTP†; Infanrix†; Pertacel†; Vacina Acel Ads Contra Dif, Tet e Coq; Vacina Comb. Contra Dif.-Tet.-Pert. Acel; Vacina Comb. Contra Difl.-Tet.-Coq.Acel; ***Canad.:*** Adacel; ***Cz.:*** Alditepera†; Boostrix; Infanrix; ***Denm.:*** Di-Te-Ki-Booster; ***Fin.:*** Boostrix; Di-Te-Kik†; Infanrix; ***Ger.:*** Boostrix; Covaxis; Infanrix; ***Gr.:*** Anatoxal Di Te Per†; DiTePer Anatoxal†; DT Coq†; Infanrix; ***Hong Kong:*** Adsorbed DT Coq†; Infanrix; Tripacel; Triple Antigen†; ***India:*** Triple Antigen; Tripvac; ***Indon.:*** Infanrix; Tripacel; ***Irl.:*** Infanrix†; ***Israel:*** Acelluvax DTP; Boostrix; DTCoq/DTP; Infanrix; ***Ital.:*** Boostrix; Infanrix; ***Malaysia:*** Boostrix; Infanrix; Tripacel†; ***Mex.:*** Boostrix; ***Neth.:*** Infanrix; ***Norw.:*** Boostrix; ***NZ:*** Boostrix; DiTePer Anatoxal; Infanrix; Tripacel; Triple Antigen; ***Philipp.:*** DPT, DT COQ; Infanrix; Tripacel; ***Pol.:*** DT Coq; DTaP, DTP; Infanrix DTPa; Tripacel; ***Port.:*** Boostrix; Infanrix; ***Rus.:*** Infanrix (Инфанрикс); ***S.Afr.:*** DTP-Merieux; Infanrix DTPa; ***Singapore:*** Boostrix; Infanrix; Tripacel; ***Spain:*** Anatoxal Di Te Per†; Boostrix; DTP-Merieux†; Infanrix; ***Swed.:*** Di-Te-Kik; Infanrix; ***Switz.:*** Boostrix; Infanrix DTPa†; ***Thai.:*** Boostrix; DTCoq/DTP; DTP Vaccine; Infanrix; Tripacel; ***Turk.:*** Acelluvax DTP; Di Te Per Anatoxal; Infanrix DTPa; Tripacel; ***UK:*** Infanrix†; Trivax-AD; ***USA:*** Adacel; Boostrix; Daptacel; Infanrix; Tripedia.

Diphtheria, Tetanus, Pertussis, and Haemophilus Influenzae Vaccines

Vacunas de la difteria, el tétanos, la tos ferina y Haemophilus influenzae.

Pharmacopoeias. Many pharmacopoeias, including *Eur.* (see p.vii), have monographs.
Ph. Eur. 6.2 (Diphtheria, Tetanus, Pertussis (Acellular, Component) and Haemophilus type b Conjugate Vaccine (Adsorbed); Vaccinum Diphtheriae, Tetani, Pertussis Sine Cellulis ex Elementis Praeparatum et Haemophili Stirpe b Conjugatum Adsorbatum). A combined vaccine composed of diphtheria formol toxoid, tetanus formol toxoid, individually purified antigenic components of *Bordetella pertussis*, polyribosylribitol phosphate derived from a suitable strain of *Haemophilus influenzae* type b and covalently bound to a carrier protein, and a mineral carrier such as aluminium hydroxide or hydrated aluminium phosphate. The product may be presented with the Haemophilus type b component in a separate container, the contents of which are mixed with the other components immediately before use. It should be stored at 2° to 8°, not be allowed to freeze, and be protected from light.

Adverse Effects and Precautions

As for vaccines in general, p.2201.

See also under Diphtheria Vaccines, p.2209, Diphtheria, Tetanus, and Pertussis Vaccines, p.2210, Haemophilus Influenzae Vaccines, p.2213, Pertussis Vaccines, p.2230, and Tetanus Vaccines, p.2240.

Interactions

As for vaccines in general, p.2202.

Uses and Administration

Combined adsorbed diphtheria, tetanus, whole-cell or acellular pertussis, and *Haemophilus influenzae* type b vaccines are available in some countries for active immunisation of children. For discussion of immunisation schedules, see under Vaccines, p.2202. Some combined vaccines are not licensed for use in primary immunisation regimens because of concerns over the response to the *Haemophilus influenzae* type b component (see under Interactions of Haemophilus Influenzae Vaccines, p.2213).

Preparations

Ph. Eur.: Diphtheria, Tetanus, Pertussis (Acellular, Component) and Haemophilus Type b Conjugate Vaccine (Adsorbed); Diphtheria, Tetanus, Pertussis (Acellular, Component), Poliomyelitis (Inactivated) and Haemophilus Type b Conjugate Vaccine (Adsorbed); Diphtheria, Tetanus, Pertussis, Poliomyelitis (Inactivated) and Haemophilus Type b Conjugate Vaccine (Adsorbed).

Proprietary Preparations (details are given in Part 3)
Arg.: Actacel; ***Austral.:*** Infanrix Hib; ***Belg.:*** Infanrix + Hib†; ***Braz.:*** Tetract-HIB†; Vacina Comb. Contra Dif.-Tet.-Pert. Acel e HIB; ***Chile:*** Actacel; Tetract-HIB; ***Cz.:*** Infanrix Hib; Tetract-HIB; ***Ger.:*** Infanrix + Hib†; ***Indon.:*** Infanrix Hib; Tetract-HIB; ***Israel:*** Infanrix Hib; Tetract-HIB; ***Malaysia:*** Infanrix Hib; Tetract-HIB†; ***NZ:*** Infanrix Hib; ***Philipp.:*** Tetract-HIB; ***Port.:*** Infanrix Hib; ***S.Afr.:*** Actacel; Combact-HIB; ***Singapore:*** Actacel; Infanrix Hib; Tetract-HIB; ***Spain:*** Infanrix Hib; Tetract-HIB†; ***Switz.:*** Infanrix DTPa-Hib†; ***Thai.:*** Actacel; Tetract-HIB; ***Turk.:*** Tetract-HIB; ***UK:*** Act-HIB DTP†; Infanrix Hib†; ***USA:*** TriHIBit; ***Venez.:*** Vacuna Tetract-HIB†.

Diphtheria, Tetanus, Pertussis, Haemophilus Influenzae, and Hepatitis B Vaccines

ATC — J07CA11.

Profile

Combined diphtheria, tetanus, pertussis, Haemophilus influenzae, and hepatitis B vaccines are available in some countries for active immunisation.

Preparations

Proprietary Preparations (details are given in Part 3)
Arg.: Tritanrix HB-HIB; ***Cz.:*** Quintanrix; ***Mex.:*** Tritanrix HB + Hiberix; ***Neth.:*** Quintanrix; ***Port.:*** Quintanrix.

Multi-ingredient: ***NZ:*** Tritanrix HB + HIB.

Diphtheria, Tetanus, Pertussis, and Hepatitis B Vaccines

Vacunas de la difteria, el tétanos, la tos ferina y la hepatitis B.
ATC — J07CA05.

Pharmacopoeias. Many pharmacopoeias, including *Eur.* (see p.vii), have monographs.
Ph. Eur. 6.2 (Diphtheria, Tetanus, Pertussis (Acellular, Component) and Hepatitis B (rDNA) Vaccine (Adsorbed); Vaccinum Diphtheriae, Tetani, Pertussis Sine Cellulis ex Elementis Praeparatum et Hepatitidis B (ADNr) Adsorbatum). A combined vaccine composed of diphtheria formol toxoid, tetanus formol toxoid, individually purified antigenic components of *Bordetella pertussis*, hepatitis B surface antigen, and a mineral carrier such as aluminium hydroxide or hydrated aluminium phosphate. It should be stored at 2° to 8°, not be allowed to freeze, and be protected from light.

Profile

Combined diphtheria, tetanus, pertussis, and hepatitis B vaccines are available in some countries for active immunisation.

Preparations

Ph. Eur.: Diphtheria, Tetanus, Pertussis (Acellular, Component) and Hepatitis B (rDNA) Vaccine (Adsorbed).

Proprietary Preparations (details are given in Part 3)
Austral.: Infanrix HepB; ***Braz.:*** Vacina Comb. Contra Dif.-Tet.-Pert.Acel e Hepat.B; ***Cz.:*** Infanrix HepB†; Tritanrix HEPB; ***Fin.:*** Infanrix HepB†; ***Gr.:*** Infanrix HepB; Infanrix-Hep†; ***India:*** Tritanrix HB; ***Indon.:*** Tritanrix HB; ***Ital.:*** Infanrix HepB†; ***Malaysia:*** Tritanrix HB; ***Mex.:*** Tritanrix HB; ***Neth.:*** Tritanrix-HepB; ***NZ:*** Infanrix HepB; ***Philipp.:*** Tritanrix HB; ***S.Afr.:*** Infanrix HB†; Tritanrix HB; ***Spain:*** Infanrix HepB†; Tritanrix HB; ***Swed.:*** Infanrix HepB†; ***Thai.:*** Tritanrix HB; ***Turk.:*** Tritanrix HB; ***Venez.:*** Tritanrix HB†.

Diphtheria, Tetanus, Pertussis, Hepatitis B, Poliomyelitis, and Haemophilus Influenzae Vaccines

ATC — J07CA09.

Pharmacopoeias. Many pharmacopoeias, including *Eur.* (see p.vii), have monographs.
Ph. Eur. 6.2 (Diphtheria, Tetanus, Pertussis (Acellular, Component), Hepatitis B (rDNA), Poliomyelitis (Inactivated) and Haemophilus type b Conjugate Vaccine (Adsorbed); Vaccinum Diphtheriae, Tetani, Pertussis Sine Cellulis ex Elementis Praeparatum, Hepatitidis B (ADNr), Poliomyelitidis Inactivatum et Haemophili Stirpe b Coniugatum Adsorbatum). A combined vaccine composed of diphtheria formol toxoid, tetanus formol toxoid, individually purified antigenic components of *Bordetella pertussis*, hepatitis B surface antigen, suitable strains of human polioviruses type 1, 2, and 3 grown in suitable cell cultures and inactivated by a validated method, polyribosylribitol phosphate derived from a suitable strain of *Haemophilus influenzae* type b and covalently bound to a carrier protein, and a mineral carrier such as aluminium hydroxide or hydrated aluminium phosphate. The product may be presented with the Haemophilus type b component in a separate container, the contents of which are mixed with the other components immediately before or during use. It should be stored at 2° to 8°, not be allowed to freeze, and be protected from light.

Profile

A combined diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis, and Haemophilus influenzae vaccine is available in some countries for active immunisation.

◊ References.

1. Curran MP, Goa KL. DTPa-HBV-IPV/Hib vaccine (Infanrix hexa). *Drugs* 2003; **63:** 673–82.

Preparations

Ph. Eur.: Diphtheria, Tetanus, Pertussis (Acellular, Component), Hepatitis B (rDNA), Poliomyelitis (Inactivated) and Haemophilus Type b Conjugate Vaccine (Adsorbed).

Proprietary Preparations (details are given in Part 3)
Arg.: Hexavac†; Infanrix Hexa; ***Austral.:*** Infanrix Hexa; ***Austria:*** Hexavac†; Infanrix Hexa; ***Belg.:*** Infanrix Hexa; ***Braz.:*** Hexavac†; Infanrix Hexa; Vacina Adsorvida Contra Dif, Tet, Coq Acel, Polio Inat Hepat B (Rec) e Hib Conj; Vacina Comb. Contra Dif.-Tet.-Pert. Acel Hepat.B r-DNA, Polio Inat e HIB; ***Chile:*** Hexavac; Infanrix Hexa; ***Cz.:*** Infanrix Hexa; ***Fin.:*** Infanrix Hexa; ***Fr.:*** Hexavac†; Infanrixhexa; ***Ger.:*** Hexavac†; Infanrix Hexa; ***Gr.:*** Hexavac†; Infanrix Hexa; Infanrix-HepB/HI†; ***Hong Kong:*** Infanrix Hexa; ***Hung.:*** Hexavac; ***Ital.:*** Hexavac†; Infanrix Hexa; ***Malaysia:*** Infanrix Hexa; ***Mex.:*** Hexavac†; Infanrix Hexa; ***Neth.:*** Infanrix Hexa; ***NZ:*** Infanrix Hexa; ***Philipp.:*** Infanrix Hexa; ***Pol.:*** Hexavac†; Infanrix Hexa; ***Port.:*** Infanrix Hexa; ***Singapore:*** Infanrix Hexa; ***Spain:*** Hexavac†; Infanrix Hexa; ***Swed.:*** Hexavac†; Infanrix Hexa; ***Switz.:*** Hexavac; Infanrix Hexa; ***Thai.:*** Infanrix Hexa; ***Venez.:*** Infanrix Hexa.

Diphtheria, Tetanus, Pertussis, and Poliomyelitis Vaccines

Vacunas de la difteria, el tétanos, la tos ferina y la poliomielitis.
ATC — J07CA02.

Pharmacopoeias. Many pharmacopoeias, including *Eur.* (see p.vii), have monographs.
Ph. Eur. 6.2 (Diphtheria, Tetanus, Pertussis (Acellular, Component) and Poliomyelitis (Inactivated) Vaccine (Adsorbed); Vaccinum Diphtheriae, Tetani, Pertussis Sine Cellulis ex Elementis Praeparatum et Poliomyelitidis Inactivatum Adsorbatum). A combined vaccine containing diphtheria formol toxoid, tetanus formol toxoid, individually purified antigenic components of *Bordetella pertussis*, suitable strains of human polioviruses type 1, 2, and 3 grown in suitable cell cultures and inactivated by a validated method, and a mineral carrier such as aluminium hydroxide or hydrated aluminium phosphate. It should be stored at 2° to 8°, not be allowed to freeze, and be protected from light.
Ph. Eur. 6.2 (Diphtheria, Tetanus, Pertussis and Poliomyelitis (Inactivated) Vaccine (Adsorbed); Vaccinum Diphtheriae, Tetani, Pertussis et Poliomyelitidis Inactivatum Adsorbatum). A combined vaccine containing diphtheria formol toxoid, tetanus formol toxoid, an inactivated suspension of *Bordetella pertussis*, suitable strains of human polioviruses type 1, 2, and 3 grown in suitable cell cultures and inactivated by a validated method, and a mineral carrier such as aluminium hydroxide or hydrated aluminium phosphate. It should be stored at 2° to 8°, not be allowed to freeze, and be protected from light.
Ph. Eur. 6.2 (Diphtheria, Tetanus, Pertussis (Acellular, Component) and Poliomyelitis (Inactivated) Vaccine (Adsorbed, Reduced Antigen(s) Content); Vaccinum Diphtheriae, Tetani, Pertussis Sine Cellulis ex Elementis Praeparatum et Poliomyelitidis Inactivatum, Antigeni-o(-is) Minutum, Adsorbatum). A combined vaccine containing diphtheria formol toxoid, tetanus formol toxoid, individually purified antigenic components of *Bordetella pertussis*, suitable strains of human polioviruses type 1, 2, and 3 grown in suitable cell cultures and inactivated by a validated method, and a mineral adsorbent such as aluminium hydroxide or hydrated aluminium phosphate. The amount of diphtheria toxoid per single human dose is reduced compared to vaccines generally used for primary vaccination; the amounts of tetanus toxoid and pertussis components may also be reduced. It should be stored at 2° to 8°, not be allowed to freeze, and be protected from light.

Adverse Effects and Precautions

As for vaccines in general, p.2201.

See also under Diphtheria Vaccines, p.2209, Diphtheria, Tetanus, and Pertussis Vaccines, p.2210, Pertussis Vaccines, p.2230, and Tetanus Vaccines, p.2240.

Interactions

As for vaccines in general, p.2202.

Uses and Administration

A combined diphtheria, tetanus, pertussis (acellular component), and poliomyelitis (inactivated) vaccine is used for active immunisation. For discussion of immunisation schedules see under Vaccines, p.2202.

In the UK it is used as part of the recommended schedule and is given by intramuscular injection in a single dose of 0.5 mL as a booster at pre-school age (3 years