

# Blood & Biologics

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## Tripedia

**Proper Name:** Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed

**Tradename:** Tripedia

**Manufacturer:** Sanofi Pasteur, Inc. License #1725

**Indications:** For active immunization against diphtheria, tetanus, and pertussis (whooping cough) as a five-dose series in infants and children 6 weeks to 7 years of age (prior to seventh birthday).

### Product Information

- [Package Insert - Tripedia \(PDF - 167KB\)](#)

### Supporting Documents

- [March 7, 2001 Approval Letter - Tripedia](#)  
Preservative-free, single dose vial presentation.
- [August 24, 2000 Approval Letter - Tripedia](#)  
5th dose at 4-6 years of age after 4 prior doses of Tripedia.
- [September 27, 1996 Approval Letter - Tripedia](#)  
For the reconstitution of Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate),

A few cases of demyelinating diseases of the CNS have been reported following some tetanus toxoid-containing vaccines or tetanus and diphtheria toxoid-containing vaccines, although the IOM concluded that the evidence was inadequate to accept or reject a causal relationship.<sup>37</sup>

Adverse events reported during post-approval use of Tripedia vaccine include idiopathic thrombocytopenic purpura, SIDS, anaphylactic reaction, cellulitis, autism, convulsion/grand mal convulsion, encephalopathy, hypotonia, neuropathy, somnolence and apnea. Events were included in this list because of the seriousness or frequency of reporting. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequencies or to establish a causal relationship to components of Tripedia vaccine.<sup>2</sup>

#### Reporting of Adverse Events

The National Vaccine Injury Compensation Program, established by the National Childhood Vaccine Injury Act of 1986, requires physicians and other health-care providers who administer vaccines to maintain permanent vaccination records of the manufacturer and lot number of the vaccine administered in the vaccine recipient's permanent medical record along with the