Shantetra®

(Combined Diphtheria, Tetanus, Pertussis and Hepatitis B Vaccine)

Prescribing Information

Qualitative and Quantitative Composition

Shantetra contains diphtheria (D), tetanus (T) toxoids, inactivated pertussis bacteria (Pw) and purified major surface antigen of the hepatitis B virus (HBV), adsorbed on aluminium salts.

The D and T toxoids are prepared from the toxins of cultures of *Corynebacterium diphtheriae* and *Clostridium tetani* by formalin inactivation using established technology. The Pw component is obtained by heat inactivation of phase I culture of *Bordetella pertussis* bacteria.

The surface antigen of the HBV (HBsAg) is produced from genetically-engineered yeast cells (*Pichia pastoris)* which carry the gene coding for the major surface antigen of the HBV. This HBsAg expressed in yeast cells is purified by several physico-chemical steps.

A single 0.5 ml dose of vaccine contains

Diphtheria toxoid	- 25 Lf
Tetanus toxoid	- 5 Lf
Wholecell *Bordetella Pertusis* killed	- 15 IOU
r-DNA HBsAg, purified	- 10 µg
Other ingredients:	
Thiomersol	- 0.025 mg
Aluminium salts	- 0.625 mg

Therapeutic Indications

Shantetra is indicated for active immunization against diphtheria; tetanus, pertussis and hepatitis B (HB) in infants from 6 weeks of age.

Posology

The recommended dose (0.5ml) of the vaccine must be administered.

The primary vaccination schedule consists of three doses within the first six months of life. Where HB vaccine is not given at birth, the combined vaccine can be administered beginning as early as 6 weeks of age. Where there is a high endemicity of HB, the practice to administer HB vaccine at birth should be continued.

Three vaccine doses must be administered at intervals of at least 4 weeks.

In the case of children born to known HB carriers mothers, the immunoprophylactic measures for hepatitis B should not be modified. This may require separate vaccination with HB and DTPw vaccines and also include the administration of HBIg at birth.

Method of Administration

Shantetra is for deep intramuscular injection, preferably in the anterolateral thigh.

It is recommended that in patients with thrombocytopenia or bleeding disorders the vaccine be administered subcutaneously.

Contra-indications

Shantetra should not be administered to subjects with either known hypersensitivity to any component of the vaccine, or having shown signs of hypersensitivity after previous administration of diphtheria, tetanus, pertussis or HB vaccines.

As with other vaccines, the administration of ***Shantetra*** should be postponed in subjects suffering from acute severe febrile illness.

Shantetra is contra-indicated if the child has experienced an encephalopathy of unknown aetiology, occurring within 7 days following previous vaccination with pertussis containing vaccine. In these circumstances the vaccination course should be continued with DT and HB vaccines.

Special precautions

Vaccination should be preceded by a review of the medical history (especially with regard to previous vaccination and the possible occurrence of undesirable events) and a clinical examination.

If any of the following events occur in temporal relation to receipt of ***Shantetra*** the decision to give subsequent doses of vaccine containing the pertussis component should be carefully considered.

- Temperature of ≥ 40ºC within 48 hours, not due to another identifiable cause;
- Collapse or shock-like state (hypnotic-hyporesponsive episode) within 48 hours;
- Persistent crying lasting ≥ 3 hours, occurring within 48 hours;
- Convulsions with or without fever, occurring within 3 days.

There may be circumstances, such as a high incidence of pertussis, when the potential benefits of the vaccine use outweigh possible risks.

A history of febrile convulsions, a family history of convulsions, SIDS (Sudden Infant Death Syndrome) or of any adverse event following ***Shantetra*** vaccination does not constitute contra-indications.

HIV infection is not considered as a contra-indication for diphtheria, tetanus, pertussis and HB vaccination. The expected immunological response may not be obtained after vaccination of immunosuppressed patients. Eg. Patients on immunosuppressive therapy.

As with all injectable vaccines, appropriate medical treatment should always be readily available in case of anaphylactic reactions following the administration of the vaccine. For this reason, the vaccinee should remain under medical supervision for 30 minutes after vaccination.

Shantetra should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects.

Shantetra **should under no circumstances be administered intravenously.**

Interactions with other medicaments and other forms of interaction

Pregnancy and lactation

As ***Shantetra*** is not intended for use in adults, information on the safety of the vaccine when used during pregnancy or lactation is not available.

Clinical Experience[1]

In a prospective phase III study 151 subjects were randomised to receive either ***Shantetra*** or the comparator vaccine. Post vaccination immune response were observed in 98.7% subjects for diphtheria, tetanus and hepatitis B vaccine components in the study vaccine group whereas 94.5% subjects responded to the diphtheria, tetanus and hepatitis B components in the comparator group. Anti-pertussis antibody response was seen in 89 and 91% in the study vaccine and comparator groups respectively. Overall the immune responses were comparable in both the groups. The subject's in the study vaccine group had a significantly higher immune response to the hepatitis B vaccine component with GMT being significantly higher than the comparator. No serious adverse events were reported in the trials.

Local side effects

The most frequently reported local reaction in both the groups was pain at the injection site, which was observed in 22.3% and 19.5% subjects in the study vaccine and comparator groups respectively followed by swelling at the site of vaccine administration.

Systemic side effects

Among the systemic events fever following vaccination was reported in 24.1% and 25.4% of infants in the study vaccine and comparator groups respectively. Fever was mild in nature and subsequently subsided within 6-12 hours following vaccination and did not recur.

Shelf-life

The expiry date of the vaccine is indicated on the label and packaging.

Special precautions for storage

Shantetra should be stored at +2ºC to +8ºC.

Do not freeze. Discard if the vaccine has been frozen.

Instruction for use/handling

How to use *Shantetra*

Shantetra is presented as suspension. Upon storage, a white deposit and clear supernatant may be observed. The vaccine should be shaken well in order to obtain a homogeneous turbid white suspension and visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either of the above being observed, discard the vaccine.

When using a multidose vial, each dose should be taken with a sterile needle and syringe. Each dose of vaccine should be withdrawn under strict aseptic conditions and precautions to avoid contamination of the contents.

Manufactured by

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