

For the use of Registered Medical Practitioner or Hospital or Laboratory only.

Rx

## Diphtheria, Tetanus, Pertussis (Whole cell) and Hepatitis B (rDNA) Vaccine (Adsorbed) I.P. **Shantetra™**

### Prescribing Information

#### Qualitative and Quantitative Composition

**Shantetra™** contains Diphtheria (D) Toxoid, Tetanus (T) Toxoid, and purified major surface antigen of the Hepatitis B virus (HBV), adsorbed on Aluminium Phosphate Gel; along with inactivated Pertussis bacteria (Pw).

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.

#### Each dose of 0.5 mL contains

Diphtheria Toxoid	≥30 IU
Tetanus Toxoid	≥60 IU
B. pertussis (Whole cell)	≥4 IU
rDNA Hepatitis B Surface Antigen	0.01 mg
Thiomersal I.P.	0.025 mg*
Aluminium Phosphate Gel equivalent to Al <sup>+++</sup>	0.625 mg
* Thiomerals content for multidose (5.0 mL) vial	0.05 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 (0.5 mL) 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 carrier 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 known hypersensitivity to any component of the vaccine, or to subjects 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 ≥ 40°C within 48 hours, not due to another identifiable cause;
- Collapse or shock-like state (hypotonic-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 presence of high fever, 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 do 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 at least 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.**

#### Administration in 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<sup>1</sup>

In a prospective multicentric phase III study 151 subjects were randomised to receive either **Shantetra™** or the comparator vaccine. Post vaccination immune response was observed in 98.9% subjects for Diphtheria, Tetanus and Hepatitis B vaccine components in the **Shantetra™** group. Whereas, 95.5% subjects responded to the Diphtheria, Tetanus and Hepatitis B components in the comparator group. Anti-pertussis antibody response was seen in 89 and 91.1% in the **Shantetra™** and comparator groups respectively. Overall the immune responses were comparable in both the groups. The subjects in the **Shantetra™** 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 **Shantetra™** and comparator groups respectively followed by swelling at 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 **Shantetra™** and comparator groups respectively. Fever was mild in nature and subsequently subsided within 6 to 12 hours following vaccination and did not recur.

#### Presentation

0.5 mL single dose vial and 5.0 mL multidose vial.

#### Shelf-life

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

#### Special precautions for storage

**Shantetra™** should be stored at + 2°C to + 8°C.

**Do not freeze.** Discard vaccine if frozen.

#### Instruction for use/handling

##### How to use **Shantetra™**

**Shantetra™** is presented as suspension. Upon storage, a white deposit may be observed. The vaccine should be **shaken adequately** in order to obtain a homogeneous turbid white suspension. The vial should be visually inspected for any foreign particulate matter. The physical aspects like cap and the seal should be inspected for integrity of container closure system. In the event of either of the above being observed, discard the vaccine.

When using a multi dose 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.

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#### Developed, Manufactured and Marketed by **Shantha Biotechnics Limited**

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