1. NAME OF THE MEDICAL PRODUCT

DIPHTHERIA-TETANUS-PERTUSSIS VACCINE ADSORBED

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 ml contains:

Diphtheria Toxoid \( \leq 25 \text{Lf} (\geq 30 \text{IU}) \)

Tetanus Toxoid \( \geq 5 \text{Lf} (\geq 40 \text{IU}) \)

B. Pertussis \( \leq 16 \text{OU} (\geq 4 \text{PU}) \)

Adsorbed on Aluminium Phosphate \((\text{AIPO}_4)\) \( \leq 1.25 \text{mg} \)

3. PHARMACEUTICAL FORM

Grayish – white suspensions

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the primary immunization of infants, above the age of six weeks, and of pre-school children against diphtheria, tetanus and whooping cough. The vaccine can be safely and effectively given simultaneously with BCG, Measles, Polio vaccines (IPV and OPV), Hepatitis B, Yellow fever Vaccine, Haemophilus influenzae-B and Varicella vaccine.

4.2 Posology and method of administration

DTP vaccine should be injection intramuscularly. The anterolateral aspect of the upper thigh is the preferred site of injection. (An injection into a child’s buttocks may cause injury to the sciatic nerve and is not recommended). It must not be injected into the skin as this may give rise to local reaction. Only sterile needles and syringes should be used for each injection. The vaccine should be well shaken before use.

Once opened, multi-dose vials should be kept between +2°C and +8°C. Multi-dose vials of DTP from which one or more doses of vaccine have been removed during an immunization session may be used in subsequent immunization sessions for upto a maximum of 4 weeks, provided that all of the following conditions are met

- The expiry date has not passed.
- The vaccines are stored under appropriate cold chain conditions;
- The vaccine vial septum has not been submerged in water;
- Aseptic technique has been used to withdraw all doses;
- The vaccine vial monitor (VVM), if attached, has not reached the discard point (see figure).
The vaccine should be visually inspected for any foreign particulate matter and/or variation of physical aspect prior to administration. In event of either being observed, discard the vaccine.

For the purpose of primary immunization it is recommended that 3 doses of 0.5 ml should be inoculated on 3 separate occasions at 4 to 6 week intervals. The first dose should be given at approximately 6 weeks of age. Reinforcing injections of 0.5 ml should be given 12 months after the primary immunization and also between the ages of 4 to 6 years.

4.3 Contraindication

Not for intradermal use. The administration of pertussis-containing vaccine is contra-indicated in children with a personal, or family history in parents or siblings of idiopathic epilepsy or other familial or hereditary diseases of the central nervous system. Administration of pertussis vaccine is also contra-indicated in children with a history of seizures, convulsions, cerebral irritation in the neonatal period, developmental neurological defect or other disorder of the central nervous system. Immunization should be postponed if the infant has an acute disease. However, low grade fever, mild respiratory infections, malnutrition or diarrhoea should not be considered as contraindications. Infants who have active or progressive neurological disease including recent convulsions should not be given pertussis-containing vaccines. Adsorbed DT vaccine should be given instead. A second or subsequent dose of DTP vaccine should not be given to a child who had a sever reaction like persistent screaming, shock, convulsions or encephalopathy to the previous dose. Adsorbed DT vaccine should be given for the remainder of the course.

4.4 Special warnings and precautions for use

It is extremely important when the parent, guardian, or adult patient returns for the next dose in the series, the parent, guardian, or adult patient should be questioned concerning occurrence of any symptoms and/or signs of an adverse reaction after the previous dose.

- HIV INFECTION

DTP vaccine may be used in children with known or suspected HIV infection. Although the data are limited and further studies are being encouraged, there is no evidence to date of any increased rate of adverse reactions using this vaccine in symptomatic or asymptomatic HIV infected children.

4.5 Interaction with other medical products and forms of interaction

If DTP and TIG of Diphtheria Antitoxin are administered concurrently, separate syringes and separate sites should be used.

As with other Intramuscular injections, use with caution in patients on anticoagulant therapy. Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids used in greater than physiologic doses, may reduce the immune response to vaccines.

4.6 Pregnancy and lactation
4.7 Effects on the ability to drive and use machines

4.8 Undesirable effects

Mild, local reactions such as pain, tenderness, erythema, induration are common and may be associated with temperature elevation (38-39°C) and an infiltration of 3 to 4 cm in diameter. Other reactions that may be observed include chills, irritability, persistent crying in infants and general malaise. Most reactions last for 24 to 48 hours: In such cases the use of antipyretics and in the case of local reaction, cold compresses should be considered. Occasionally a nodule may develop at the site of injection but this is without any harmful effects. More serious reactions such as fever above 40°C excessive screaming, and encephalopathic symptoms (e.g. convulsions) may also be observed but are extremely rare. By strict observance of the contraindications listed below the number of such complications will be reduced to a minimum.

4.9 Overdose

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Each 0.5 ml contains:

Thiomersal 0.01%

6.2 Incompatibilities

6.3 Shelf life

24 months from date of manufacture.

6.4 Special precautions for storage

The vaccine should be stored in a dry, dark place at a temperature between 2-8°C. Transportation should also be at 2-8°C. Do not freeze.

6.5 Nature and contents of container
6.6 Special precautions for disposal and other handling

7. MARKETING AUTHORISATION HOLDER
   MASU CO., LTD.

8. MARKETING AUTHORISATION NUMBER (S)
   3/2536

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION
   30 September 2004

10. DATE OF REVISION OF THE TEXT
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