SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Product Name: EasySix Vaccine

Purified Diphtheria Toxoid, Purified Tetanus Toxoid, Whole cell Pertussis, Recombinant Hepatitis B, *Haemophilus influenzae* Type b Conjugate and Inactivated Poliomyelitis Trivalent Vaccine (Adsorbed) [DTwP-HepB-Hib-IPV].

Strength: One pediatric dose is 0.5 ml

Pharmaceutical Form: Injectable Vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative and quantitative composition for EasySix vaccine is as given in table below:-

Single paediatric dose of 0.5 ml contains:

Ingredients	**Quantity per dose of 0.5 ml**
Diphtheria Toxoid	≥ 30 IU
Tetanus Toxoid	≥ 60 IU
Inactivated Whole cell Pertussis	≥ 4 IU
r Hepatitis B surface Antigen	≥ 10 µg
H. influenzae type b conjugated (PRP-TT)	10 µg
Inactivated Salk Polio Virus Type 1	40 DU
Inactivated Salk Polio Virus Type 2	8 DU
Inactivated Salk Polio Virus Type 3	32 DU
Aluminium content (Al^{3+}) (as Aluminium Phosphate gel)	NMT 1.25 mg
2-phenoxyethanol	3.3 mg
Physiological saline	q.s.

3. PHARMACEUTICAL FORM

The final product has an appearance of a pink to light pink to off-white, suspension in which the mineral carrier (aluminum phosphate gel) tends to settle down slowly on keeping.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

EasySix is indicated for primary and booster vaccination of infants and toddlers from six weeks to 5 years of age against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and severe infection caused by *Haemophilus influenzae* type b.

4.2 Posology and method of administration:

One paediatric dose is of 0.5 ml.

The vaccine should be well shaken to get a uniform suspension before use. The site of injection should be prepared with a suitable antiseptic. The vaccine should be administered by intramuscular route. The preferred injection site for infants is antero-lateral aspect of thigh. Do not inject intravenously or subcutaneously.

4.3 Contraindications:

Hypersensitivity to the active substances, to any of the excipients, to any pertussis vaccine, or after previous administration of the vaccine or a vaccine containing the same components or constituents.

Generally vaccination must be postponed in cases of moderate or severe febrile and/or acute disease. The presence of a minor infection and/or low-grade fever does not constitute a contraindication.

The vaccination with **EasySix** is contraindicated if the infant has experienced an encephalopathy of unknown aetiology, occurring within 7 days following previous vaccination with pertussis containing vaccine. In these circumstances pertussis vaccination should be discontinued and the vaccination course should be continued with diphtheria-tetanus, hepatitis B, polio and Hib vaccines.

Uncontrolled neurologic disorder or uncontrolled epilepsy: Pertussis vaccine should not be administered to individuals with these conditions until the treatment regimen has been established, the condition has stabilized and the benefit clearly outweighs the risk.

4.4 Special warnings and precautions for use:

EasySix 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 the administration of **EasySix vaccine** the decision to give subsequent doses of vaccine containing the pertussis component should be carefully considered:

- Temperature of ≥40.0 ˚C within 48 hours, not due to another identifiable cause
- Collapse or shock-like state (hypotonic-hypo responsive episode) within 48 hours
- Persistent crying lasting >3 hours, occurring within 48 hours
- Convulsions with or without fever, occurring within 3 days.

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

HIV infection is not considered as a contra-indication for diphtheria, tetanus, pertussis, hepatitis B, Hib and polio vaccination. The expected immunological response may not be obtained after vaccination of Immunosuppressed patients, e.g. 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 vaccine should remain under medical supervision for 30 minutes after vaccination.

EasySix vaccine should under no circumstances be administered intravenously or subcutaneously.

4.5 Interaction with other medicinal products and other forms of interaction:

EasySix may be co-administration with another vaccine is considered, immunization should be carried out on separate injections sites.

EasySix must not be mixed with any other vaccines or other parenterally administered medicinal products. The immunological response of the vaccine may be reduced in patients undergoing therapy with corticosteroids or immunosuppressant.

4.6 Pregnancy and lactation:

Not Applicable, as EasySix vaccine is not intended for use in adolescent and adult population .

4.7 Effects on ability to drive and use machines:

Not Applicable, as EasySix is not intended for use in adult.

4.8 Undesirable effects:

In a randomized clinical study of **EasySix** *(Panacea Biotec Ltd)* with comparator pentavalent co-administered with Inactivated Polio Vaccine (IPV) vaccine in healthy infants following adverse events were reported.

Local symptoms like pain / tenderness, redness and swelling may be observed after the administration of the vaccine. A small lump may occasionally be noted in the site of the inoculation that disappears after few days.

Systemic symptoms observed include the fever, drowsiness, irritability, persistent crying, loss of appetite, and vomiting.

These symptoms were resolved within 48 hours after vaccination.

4.9 Overdose:

Not Applicable, as EasySix vaccine is to be administered as per the pediatric immunization schedule under the direct supervision of physicians.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Immunogenicity of EasySix vaccine was evaluated in 6, 10, 14 weeks schedule (3 doses given at 4 weekly intervals). The seroprotection rates/ immune responses for the all components of the vaccine after 1 month completion of 3-dose primary vaccination schedule were as follows: Anti-diphtheria, anti-tetanus and anti-HBsAg seroprotection rate was 94.85%, 100% and 97.79%, respectively. The anti-PRP seroprotection rate was 100% for short term and 92.65% for long term protection. The pertussis IgG and anti-PT response rate was 75.74% and 68.38%, respectively. The seroconversion rate against polio type 1, type 2 and type 3 was 89.71%, 93.38% and 88.24%, respectively.

Clinical Studies

The safety and efficacy of EasySix vaccine has been evaluated in 6, 10, 14 weeks schedule (3 doses given at 4 weeks intervals). The immune responses for all the four components of the vaccine was non inferior to the licensed control vaccine.

5.2 Pharmacokinetic properties:

Not Applicable.

5.3 Preclinical safety data:

Panacea Biotec manufactured the combination vaccines i.e. EasySix (DTwP^{PEBL}-HepB^{PEBL}-Hib^{PEBL}-IPV^{BBV}), hexavalent vaccine by utilizing the Diphtheria toxoid, Tetanus toxoid, Inactivated whole cell *B. pertussis*, Purified capsular polysaccharide (PRP) from *Haemophilus influenzae* type b conjugated to tetanus toxoid, Hepatitis B surface antigen from PanEra Biotec Pvt. Ltd., Lalru and Inactivated Poliomyelitis viruses (Salk strains)Type 1, 2 & 3 from Bilthoven Biologicals B.V.

All the Six individual components i.e. Inactivated whole cell *B. pertussis*, Purified capsular polysaccharide (PRP) from *Haemophilus influenzae* type b conjugated to tetanus toxoid, Hepatitis B surface antigen manufactured by PanEra Biotec Pvt. Ltd., Lalru are well established one and proven to be safe, as, same are being used successfully since last many decades in immunization history and Inactivated Poliomyelitis viruses (Salk strains) Type 1, 2 & 3 procured from M/s Bilthoven Biologicals B.V is safe.

Based on the single dose and repeat dose toxicity studies in Balb/c mice and New Zealand white rabbits, EasySix vaccine (DTwP-HepB-Hib-IPV) did not show any adverse effect when administered either as single dose or repeated injection by intramuscular route.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

- Aluminum phosphate gel
- 2 - phenoxyehanol
- Physiological saline
- Water for injection

6.2 Incompatibilities:

The vaccine should not be mixed in the vial or syringe with any other vaccine.

6.3 Shelf life:

24 months from the date of manufacturing, when stored at 5°C ± 3°C.

6.4 Special precautions for storage:

The vaccine should be stored and transported at temperature between 5 ± 3°C until the expiry date indicated on the Pre Filled Syringe (PFS) or Vial label/pack. The vaccine must not be frozen.

6.5 Nature and contents of container:

The vaccine in single dose, 0.5ml is filled in Prefilled Syringes (USP Type 1 glass) and stoppered with plunger stopper and in glass vials in single and multidose presentation.

7. MARKETING AUTHORIZATION HOLDER

Panacea Biotec Ltd.
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Himachal Pradesh – 173205, India
Tel. : 01795-674000
E-mail : corporate@panaceabiotec.com
Website: https://www.panaceabiotec.com

8. MARKETING AUTHORIZATION NUMBER(S)

MF-186/2016 dated 16.11.2016

License No. : MB/07/632

9. DATE OF FIRST AUTHORIZATION/ RENEWAL OF THE AUTHORIZATION

The details of the manufacturing authorization certificates obtained from Licensing Authority, India for EasySix vaccine manufactured at Vaccine Formulation Plant (VFP), Baddi, Himachal Pradesh, India are as mentioned below:

- Date of first authorization: 02.01.2017
- Renewal of the authorization: granted on September 29, 2017 valid up to 28.09.2022.
- Retained up to 28.09.2027