SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Product Name: Adsorbed Diphtheria, Tetanus, Pertussis, Poliomyelitis (Inactivated) and *Haemophilus Influenzae* Type b Conjugate Vaccine IP

Brand Name: EasyFourPol®

Strength: One pediatric dose is 0.5 ml

Dosage Form: Suspension of injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

The composition for **EasyFourPol®** (DTwP-Hib-IPV) vaccine is as given in table below:-

Component	**Qty /0.5 ml**
Diphtheria Toxoid	≥ 30 IU
Tetanus Toxoid	≥ 60 IU
Inactivated w-B.*pertussis*	≥ 4 IU
Haemophilus influenzae type b conjugate	10 µg
Inactivated Salk Poliovirus Type 1*	40 DU
Inactivated Salk Poliovirus Type 2*	8 DU
Inactivated Salk Poliovirus Type 3*	32 DU
Al^{3+} Aluminium phosphate gel	NMT 1.25 mg
2-phenoxyethanol	3.3 mg
Physiological saline	q.s.

** Bulk source: Bilthoven Biologicals B.V. Netherlands, Cell substrate: Vero cells; DU : D-antigen units*

SUMMARY OF PRODUCT CHARACTERISTICS

3. PHARMACEUTICAL FORM

EasyFourPol® vaccine (DTwP-Hib-IPV) is light pink to off white suspension in which the mineral carrier (aluminium phosphate gel) tends to settle down slowly on keeping. It gives protection against infectious diseases such as Diphtheria, Tetanus, Pertussis, Poliomyelitis & severe infections caused by *Haemophilus influenzae* Type b.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

Active immunization for prevention against Diphtheria, Tetanus, Pertussis (Whooping Cough) severe infections caused by *Haemophilus influenzae* Type b and Poliomyelitis.

4.2 Posology and method of administration:

One paediatric dose is of 0.5 ml.

The vaccination should be given by medical or healthcare professionals who are trained in the use of vaccines and who are equipped to deal with any uncommon severe allergic reaction to the injection. EasyFourPol® is indicated for active immunization of infants, it is recommended that 0.5ml each of 3- intramuscular injections of EasyFourPol® vaccine to be administered in the antero-lateral aspect of thigh with an interval of four weeks between doses, starting at 6 weeks of age.

The customary age for the first dose of primary immunization is recommended to be 6 weeks of age. Specifically, Indian Academy of Pediatrics (IAP) recommends DTwP, Hib and polio to be given at 6, 10 and 14 weeks of birth. Hence, the combination of EasyFourPol® can be given at 6, 10 and 14 weeks.

A booster dose of DTwP, Hib and polio is recommended at the age of 15-18 months.

A reinforcing injection of the DTwP combination should be administered at 5 years of age (i.e.at the time of school entry).

DO NOT INJECT INTRAVENOUSLY OR SUBCUTANEOUSLY

If you forget one dose of EasyFourPol®.
If your child misses a scheduled injection, it is important that you discuss with your doctor or nurse who will decide when to give the missed dose. It is important to follow the instructions from the doctor or nurse so that your child completes the course of injections. If not, your child may not be fully protected against the diseases. If you have any further questions on the use of this vaccine, ask your doctor, pharmacist or nurse.

4.3 Contraindications:

EasyFourPol® should not be administered to subjects with known Hypersensitivity to any component of the Vaccine or to subjects who have shown signs of Hypersensitivity after previous administration of Diphtheria, Tetanus, Pertussis, Hib and IPV vaccines.

4.4 Special warnings and precautions for use:

EasyFourPol® 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 EasyFourPol® 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 EasyFourPol® vaccination does not constitute contra- indications.

HIV infection is not considered as a contra-indication for diphtheria, tetanus, pertussis, 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.

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

Tell your doctor or pharmacist if your child is taking, has recently taken any other medicines or might take any other medicines. EasyFourPol® can be given at the same time as other vaccines such as pneumococcal polysaccharide conjugated vaccines, measles-mumps-rubella vaccines or rotavirus vaccines. Your doctor will give the injections at different sites and will use separate syringes and needles for each injection.

4.6 Pregnancy and lactation:

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

4.7 Effects on ability to drive and use machines:

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

4.8 Undesirable effects:

Like all medicines, **EasyFourPol®** can cause side effects, although not everybody gets them. In a randomized phase II/III clinical study of **EasyFourPol®** in healthy infants following adverse events were reported.

- Very common side effects (may affect more than 1 in 10 people)
    - Pain/ tenderness
    - Fever
    - Swelling
- Common side effects (may affect up to 1 in 10 people)
    - Diarrhoea
    - Excessive sleepiness/drowsiness
    - Irritability/Restlessness/Fussiness
    - Poor eating
    - Vomiting

- Uncommon side effects (may affect up to 1 in 100 people)
    - Acute allergic reaction

Most of these symptoms were resolved within 48 hours after vaccination.

4.9 Overdose:

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

In Phase II/III clinical study, immunogenicity of EasyFourPol® 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 and anti-tetanus seroprotection rate was 96.64% and 100% respectively. The anti-PRP seroprotection rate was 97.48%. The pertussis IgG and anti-PT response rate was 47.90% and 78.99%, respectively. The Seroconversion rate against polio type 1 and type 3 was 94.12% & 98.32%, respectively. The test for detection of serum antibodies against type 2 poliovirus was not performed due to non-availability of type 2 live virus required for testing. This is in conformance to WHO's laboratory containment strategy to destroy type 2 poliovirus from serology laboratories.

Clinical Studies

The safety and efficacy of Immunogenicity of EasyFourPol® vaccine was evaluated in 6, 10, 14 weeks schedule (3-doses given at 4 weekly intervals). The immune responses for all the five components of the vaccine were non inferior to the licensed control vaccines.

5.2 Pharmacokinetic properties:

Not Applicable.

5.3 Preclinical safety data:

Panacea Biotec manufactured the combination vaccines i.e. EasyfourPol (DTwP-Hib-IPV), 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 from Panacea Biotec Ltd., Lalru and Inactivated Poliomyelitis viruses (Salk strains)Type 1, 2 & 3 from Bilthoven Biologicals B.V.

All the five individual components i.e. Diphtheria toxoid, Tetanus toxoid, Inactivated whole cell *B. pertussis*, Purified capsular polysaccharide (PRP) from *Haemophilus influenzae* type b conjugated to tetanus toxoid are manufactured by Panacea Biotec Ltd., Lalru are well established one and proven to be safe, as, same are being used successfully since last many decades in immunization history. Trivalent bulk of Inactivated Poliomyelitis (Salk strains) Type 1, 2 & 3 procured from M/s Bilthoven Biologicals B.V , Netherlands is also proven to be safe and prequalified from WHO..

In addition, the single dose and repeat dose toxicity studies in Balb/c on EasyfourPol vaccine (DTwP-Hib-IPV) were conducted by Panacea Biotec Ltd and based upon these studies the vaccine has been found to be safe and not shown 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 - Phenoxyethanol
- Physiological saline

6.2 Incompatibilities:

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

6.3 Shelf life:

36 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 Vial label/pack. The vaccine must not be frozen.

6.5 Nature and contents of container:

EasyFourPol® Vaccine is filled in single dose (0.5 ml) presentation in USP Type 1 glass vial & stoppered with bromo-butyl rubber bungs and sealed with flip off aluminium seals.

7. MARKETING AUTHORIZATION HOLDER

Panacea Biotec Ltd.
Malpur, Baddi, Distt Solan,
Himachal Pradesh – 173205, India
Tel. : 01795-674036
E-mail : corporate@panaceabiotec.com
Website: https://www.panaceabiotec.com

8. MARKETING AUTHORIZATION NUMBER(S)

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 EasyfourPol vaccine manufactured at Vaccine Formulation Plant (VFP), Baddi, Himachal Pradesh, India are as mentioned below:

- Date of first authorization: 21 September, 2022
- Retained upto September 28, 2027