

Size : 95 x 245 mm

Rx For the use of Registered Medical Practitioner or a Hospital or a Laboratory only

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

Fully Liquid Pentavalent Vaccine
EasyFourPol[®]
(DTwP-Hib-IPV)

Read all of this leaflet carefully before your child is vaccinated because it contains important information for him/her.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

Warning: To be sold by retail on the prescription of the registered medical practitioner

What EasyFourPol[®] contains

One dose of 0.5 ml contains:

Diphtheria Toxoid	≥ 30 IU
Tetanus Toxoid	≥ 60 IU
Inactivated w-9 pertussis	≥ 4 IU
Purified capsular polysaccharide of <i>Haemophilus influenzae</i> type b conjugated to 18-33 µg of Tetanus Toxoid (carrier protein)	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.

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

What is in this leaflet:

- EasyFourPol[®] description, usage and indication
- What to know before EasyFourPol[®] is administered to your child
- How to administer EasyFourPol[®]
- Possible side effects
- How to store EasyFourPol[®]
- Contents of the pack and other information

1. EasyFourPol[®] description, usage and indication

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.

The vaccine induces the body to produce antibodies which protects against the bacteria and viruses causing the following infections:

- Diphtheria is an infectious bacterial disease that tends to first affect the throat causing pain and swelling which can ultimately result in suffocation. A toxin that can damage the heart, kidneys and nerves may also be produced.
- Tetanus tends to be caused by the tetanus bacteria especially in penetrating deep wounds. The disease is dangerous since the bacteria can produce a toxin which can cause spasms of the muscles of the back & respiratory muscles, leading to breathing difficulties & even suffocation.
- Pertussis (whooping cough) affects primarily the airways. The infection affects infants and young children mostly but adolescents or adults may also be affected. The condition is characterized by severe cough spells that can last for weeks. Typically a 'whoop' noise may follow the coughing spells.
- Poliomyelitis is a viral disease that can cause paralysis of legs commonly. It may also affect muscles controlling breathing and swallowing, wherein the condition can be fatal.
- Haemophilus influenzae* type b can cause serious infections such as meningitis, inflammation of the lungs, tissue under the skin, joints and bones and throat.

Important information about the protection provided

- EasyFourPol[®] will only help to prevent these diseases if they are caused by the bacteria or viruses targeted by the vaccine.
- This vaccine does not contain any live bacteria or viruses and it cannot cause any of the infectious diseases against which it protects.
- This vaccine does not protect against infections caused by other types of *Haemophilus influenzae* nor against meningitis due to other microorganisms.

Indication: Active immunization for prevention against Diphtheria, Tetanus, Pertussis (Whooping Cough), infections caused by *Haemophilus influenzae* Type b & Poliomyelitis

2. What to know before EasyFourPol[®] is given to your child

It is important to talk to your doctor or nurse if any of the points below apply to your child. Ask your doctor, pharmacist or nurse, if you do not understand

Do not use EasyFourPol[®] if your child has had an allergic reaction:

- to the active substances,
- to any of the excipients
- to any pertussis vaccine (any vaccine that protects against whooping cough),
- after previous administration of the vaccine or to any 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 EasyFourPol[®] should not be administered if the infant has experienced an encephalopathy of unknown etiology, 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.

SPECIAL WARNING AND PRECAUTION

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 $\geq 40.0^{\circ}\text{C}$ 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 vaccinee should remain under medical supervision for 30 minutes after vaccination.

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.

Other medicines or vaccines and EasyFourPol[®]

Tell your doctor or pharmacist if your child is taking, has recently taken any other medicines or might take any other medicines. Your doctor will give the injections at different sites and will use separate syringes and needles for each injection.

3. How to administer EasyFourPol[®]

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.

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.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties:

Pharmacotherapeutic Group: Bacterial and viral combined vaccines against diphtheria, tetanus, pertussis, *Haemophilus influenzae* Type b and poliomyelitis

Clinical Trials

In Phase III/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 Serocomversion 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.

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.

Table 1: Differences in Seroprotection/Immune Response Rates between Groups, with 95% CIs (Immunogenicity Cohorts)

Antibody	EasyFourPol [®] (N=119)		Tetravalent DTwP/Hib co-administered with Imovax [®] Polio (N=118)		Difference in Seroprotection Rate (Quadrovax [®] co-administered with Imovax [®] Polio - EasyFourPol [®])		
	N	n (%)	N	n (%)	Difference in %	95% CI	
Antigen						LL	UL
Anti-PT (µg/ml)	119	94(78.99)	118	91(77.12)	-1.87	-12.41	8.66
Anti-Diphtheria (IU/ml)	119	115(96.64)	118	118(100.00)	3.36	0.08	6.64
Pertussis IgG (IU/ml)	119	57(47.90)	118	49(41.53)	-6.37	-19.03	6.29
Anti-PRP* (µg/ml)	119	116(97.48)	118	118(100.00)	2.52	-0.33	5.37
Anti-PRP** (µg/ml)	119	112(94.12)	118	114(96.61)	2.49	-2.86	7.85
Anti-Tetanus (IU/ml)	119	119(100.00)	118	116(98.31)	-1.69	-4.02	0.63
Anti-Polio virus Type 1 (IU/ml)	119	112(94.12)	118	109(92.37)	-1.74	-8.13	4.64
Anti-Polio virus Type 3 (IU/ml)	119	117(98.32)	118	115(97.46)	-0.86	-4.52	2.80

*The Anti-PRP seroprotection rate (≥ 0.15).

**The Anti-PRP seroprotection rate (≥ 1.0).

4. Possible Side effects

Like all medicines, EasyFourPol[®] can cause side effects, although not everybody gets them.

In a randomized phase III/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
- redness/erythema
- Swelling

Common side effects (may affect up to 1 in 10 people)

- Diarrhea
- 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.

Other side effects:

Serious allergic reactions are a very rare possibility. If any of these symptoms occur after leaving the place where your child received his/her injection, you must consult a doctor IMMEDIATELY.

- difficulty in breathing
- arash
- swelling of the face or throat
- low blood pressure causing dizziness or collapse. When these signs or symptoms occur they usually develop quickly after the injection is given and while the child is still in the clinic.

Other side effects not listed above have been reported occasionally with other diphtheria, tetanus, pertussis, poliomyelitis or Hib containing vaccines and not directly with EasyFourPol[®] are temporary inflammation of nerves causing pain, paralysis and sensitivity disorders (Guillain-Barre syndrome/ GBS) and severe pain and brachial neuritis has been reported after administration of a tetanus containing vaccine. If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

In case you experience any undesirable effect following intake of this medication please feel free to contact us at any of the following contact details: e-mail id: pvg@panaceabiotec.com; Fax no.: +91-11-41578065; M. No. +91-9650138282.

5. How to store EasyFourPol[®]

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is mentioned on the carton and the label

Store in refrigerator between $5 \pm 3^{\circ}\text{C}$. DO NOT FREEZE.

6. Contents of the pack and other information

PRESENTATION

Single dose vial containing 0.5 ml vaccine

WITHDRAWING THE VACCINE FROM A VIAL

Shake the vial to disperse the contents thoroughly immediately before each withdrawal of vaccine.

Remove the flip of seal and a small circular portion of rubber stopper is seen.

DO NOT REMOVE THE RUBBER STOPPER FROM THE VIAL.

Apply a sterile piece of cotton moistened with a suitable antiseptic to the surface of the rubber stopper and allow to dry. Draw into the sterile syringe a volume of air equal to the amount of vaccine to be withdrawn from the vial. Pierce the centre of the rubber stopper with the sterile needle of the syringe, invert the vial, slowly inject into it, the air contained in the syringe, and keeping the point of the needle immersed, withdraw into the syringe the required amount of vaccine. Then hold the syringe plunger steady and withdraw the needle from the vial.

Carefully insert the needle intramuscularly at the prepared injection site.

Manufactured by:
Panacea Biotech Ltd.
Malpur, Baddi, Distt. Solan (H.P.) - 173 205, India.

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Panacea Biotech
Innovation in support of life

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