What is in this leaflet:

1. EasySix™ description, usage and indication
2. What to know before EasySix™ is administered to your child
3. How to administer EasySix™
4. Possible side effects
5. How to store EasySix™
6. Contents of the pack and other information

1. EasySix™ description, usage and indication
EasySix™ vaccine (DTPw-HepB-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, Hepatitis B & severe infections caused by Haemophilus influenzae Type b.

This 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 can produce a toxin which can cause spasms of the muscles of the back & respiratory muscles, leading to breathing difficulties & even suffocation.
- Hepatitis B is a viral disease characterized by inflammation of Liver. The condition can be fatal. It may also affect muscles controlling breathing and swallowing, when 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
- EasySix™ 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.
- This vaccine does not protect against hepatitis infection caused by other agents such as Hepatitis A, Hepatitis C and Hepatitis E or by other liver pathogens.

Indication: For active immunization (for prevention) against Diphtheria, Tetanus, Pertussis (Whooping Cough), Hepatitis B, Infections caused by Haemophilus influenzae Type b & Poliomyelitis.

2. What to know before EasySix™ 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:
- Your child has had an allergic reaction to any of the active substances,
- to any of the excipients
- to any pertussis vaccine (any vaccine that protects against whooping cough),
- 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-hyporesponsive episode) within 48 hours
- Persistent crying lasting >3 hours, occurring within 48 hours
- Convulsions with or without fever, occurring within 3 days.
- Other medicines or vaccines and EasySix™
- Tell your doctor or pharmacist if your child is taking, has recently taken any other medicines or might take any other medicines. EasySix™ can be given at vaccination course should be continued with diphtheria-tetanus, hepatitis B, polio and Hib vaccines.
- Uncontrolled neurological 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
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.

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The completion of 3-dose primary vaccination schedule were as follows: Anti-immune responses for the all components of the vaccine after 1 month schedule (3-doses given at 4 weekly intervals). The seroprotection rates/Immunogenicity of this vaccine, ask your doctor, pharmacist or nurse.

**PHARMACOLOGICAL PROPERTIES**

- Your doctor will give the injections at different sites and will use separate syringes and needles for each injection.
- Do not inject intravenously or subcutaneously.
- If you have any further questions on the use of this vaccine, ask 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 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.
- A reinforcing injection of the DTwP combination should be administered at 5—15-18 months.
- 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 DTP7, hepatitis B, Hib and polio to be given at 6, 10 and 14 weeks of birth. Hence, the combination of EasySix™ can be given at 6, 10 and 14 weeks.
- 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.
- DO NOT INJECT INTRAVENOUSLY OR SUBCUTANEOUSLY.

**3. How to administer EasySix™**

- If your child has 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 your child gets any side effects, talk to your doctor, pharmacist or nurse.