Act-HIB 10 micrograms/0.5 mL,
Powder and solvent for solution for injection in pre-filled syringe.

*Haemophilus* type b conjugate vaccine

Please read this package leaflet carefully before getting vaccinated.
- Keep this leaflet. You may need to read it again.
- If you have further questions, if you have a doubt, ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell you doctor or pharmacist. See section 4.

What is in this leaflet:
1. What Act-HIB is and what it is used for
2. What you need to know before you use Act-HIB
3. How to use Act-HIB
4. Possible side effects
5. How to store Act-HIB
6. Further information

1. WHAT Act-HIB IS AND WHAT IT IS USED FOR

Act-HIB is a vaccine. Vaccines are used to protect against infectious diseases. When Act-HIB is injected, the body’s natural defenses develop a protection against those diseases.

This vaccine is indicated for the prevention of *Haemophilus influenzae* type b invasive infections (meningitis, septicaemia, cellulitis, arthritis, epiglottitis, etc.) in children from the age of 2 months.

This vaccine does not protect against infections due to other types of *Haemophilus influenzae* or against meningitis of other origins.

Under no circumstances can the tetanus protein contained in this vaccine be used to replace the usual tetanus vaccination.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE Act-HIB

Do not use Act-HIB
- If your child is allergic (hypersensitive) to any of the vaccine components (listed in section 6 Further information), to the tetanus protein, to formaldehyde, or if your child had an allergic reaction following injection of a vaccine containing the same substances,
- If your child had an allergic reaction following prior injection of an *Haemophilus influenzae* type b conjugate vaccine,
- If your child has fever or a disease that occurred suddenly, without warning (acute disease), in this case it is preferable to postpone the vaccination.

Warnings and precautions
Talk to your doctor before using Act-HIB
If your child has a weakened immune system, or if your child is treated with corticosteroids, cytotoxic drugs, radiotherapy of other drugs likely to weaken the immune system. Your doctor may wait until the end of the treatment.

- If your child has bleeding disorders such as a decrease in platelets (thrombocytopenia) or clotting disorders, because of the risk of bleeding which may occur during intramuscular administration.

Other medicines and Act-HIB
In case of concomitant administration of this vaccine with a measles, mumps and rubella vaccine or with vaccines against diphtheria, tetanus, pertussis and poliomyelitis, the two injections will be performed at two separate sites, which means in another part of the body such as the other arm or the other leg.

Please tell you doctor or pharmacist if your child is taking or has recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy – Breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

3. HOW TO USE Act-HIB
Dosage:
- Before 6 months of age, 3 successive doses of 0.5 ml administered one or two months apart, followed by a booster injection (0.5 ml) one year after the third injection.
- Between 6 and 12 months of age, 2 doses of 0.5 ml administered one month apart, followed by a booster injection (0.5 ml) at 18 months of age.
- From 1 to 5 years of age, a single dose of 0.5 ml.

For contact cases: In the event of a contact with a case of invasive *Haemophilus influenzae* type b infection (family or childcare), vaccination should be implemented according to the schedule for the contact case’s age.

The index case (the first case identified in an organisation or a community) must also be vaccinated.

Method of Administration:
- This vaccine will be administered to your child by a healthcare professional preferably into a muscle or deep under the skin, into a thigh or into an arm.

This vaccine must never be administered into a blood vessel.

If you forget to use Act-HIB:
If you forget to take one dose of the vaccine, your doctor will decide when to administer this dose.

If you have any further question on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS
Like all medicines, Act-HIB can cause side effects, although not everybody gets them.

Very common side effects (reported by more than 1 in 10 people):
- Injection-site reactions such as pain, redness, swelling and/or inflammation, hardening (induration)
- Irritability

Common side effects (reported by less than 1 in 10 people but more than 1 in 100 people):
- crying (incontrollable or abnormal),
- fever,
- vomiting.

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Uncommon side effects (reported by less than 1 in 100 people but more than 1 in 1000 people):
- fever (higher than 39°C):

Side effects with a not known frequency (because reported voluntarily and very rarely):
- extensive swelling (large oedema) of the vaccinated limb that may spread to the whole arm or leg into which the vaccine was administered,
- large injection site reactions, larger than 5 cm, such as pain, redness (erythema), swelling (oedema) and/or inflammation, or hardening of the skin (induration),
- swelling of legs and feet (oedematous reactions affecting lower limbs). These reactions may be associated with crying, bluish skin colour (cyanosis) or redness and small transient red spots (purpura) occurring in the first hours of vaccination, resolving quickly without treatment (within 24 hours) and without sequelae,
- swelling of the face and/or neck, allergic reactions (hypersensitivity reactions),
- convulsions associated or not with fever,
- skin eruption, sometimes swollen and itchy (urticaria, rash, pruritus).

In babies born very prematurely (at or before 28 weeks of gestation) longer gaps than normal between breaths may occur for 2-3 days after vaccinations.
If you notice any side effects not listed in this package leaflet, please tell your doctor or pharmacist.

**Reporting of side effects**
If you or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

**5. HOW TO STORE Act-HIB**
Keep out of the sight and reach of children.

Do not use after the expiry date which is stated marked on the box after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C).
Do not freeze.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. FURTHER INFORMATION**

**What Act-HIB contains**
- The active substance is:
  Haemophilus influenzae type b polysaccharide (10 micrograms per 0.5 mL dose) conjugated to tetanus protein (18 - 30 micrograms per 0.5 mL dose).
- The other ingredients are:
  For the powder: trometamol and sucrose.
  For the solvent: sodium chloride and water for injections.

**What Act-HIB looks like and contents of the pack**
This vaccine comes in the form of a vial of powder and a solution for injection of solvent (0.5 mL in pre-filled syringe with or without attached needles). Box of 1. The powder is white and the solvent is colourless. Not all pack sizes may be marketed.

**Holder**
SANOFI PASTEUR  
2, AVENUE PONT PASTEUR  
69007 LYON  
FRANCE

**Distributor**
SANOFI PASTEUR MSD SNC 12, RUE JONAS SALK  
69007 LYON  
FRANCE

**Manufacturer**
SANOFI PASTEUR  
2, AVENUE PONT PASTEUR 69007 LYON FRANCE

This leaflet was last revised in: 06/2015

**Method of administration**

Reconstitute the solution, either by injecting the content of the syringe or ampoule of solvent into the vial of powder or by injecting the content of a syringe of combined diphtheria-tetanus-pertussis vaccine or a diphtheria-tetanus-pertussis-poliomyelitis vaccine.  
- Shake until the powder is completely dissolved.  
The whitish, cloudy appearance of the suspension following reconstitution by a syringe of diphtheria-tetanus-pertussis vaccine or a diphtheria-tetanus-pertussis-poliomyelitis vaccine is normal.  
For syringes without attached needle, the separate needle must be fitted firmly rotating it by a one-quarter turn.  
Do not inject by intravascular route.  
Any unused product or waste material should be disposed of in accordance with the regulation in effect.

Administer via the intramuscular (preferably) or the deep-subcutaneous route: the recommended injection sites are the antero-lateral aspect of the thigh (middle third) for infants and toddlers and the deltoid region for older children.

**Interaction with other medicinal products and other forms of interaction**

Since the Hib capsular polysaccharide antigen is excreted in urine, a positive urine test can be observed within 1 to 2 weeks following vaccination. Other tests must be performed in order to confirm Hib infection during this time.