

## READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

### PART III: PATIENT MEDICATION INFORMATION

#### Act-HIB<sup>®</sup>

#### Haemophilus b Conjugate Vaccine (Tetanus Protein – Conjugate)

Read this carefully before Act-HIB<sup>®</sup> is given to you or your child. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your (or your child's) medical condition and treatment and ask if there is any new information about Act-HIB<sup>®</sup>.

#### What is Act-HIB<sup>®</sup> used for?

Act-HIB<sup>®</sup> is a vaccine that protects against infection with *Haemophilus influenzae* type b (Hib). Hib causes bacterial meningitis and other serious infections. All children 2 months to 5 years of age should receive Hib vaccine, usually combined with QUADRACEL<sup>®</sup>. Children over 5 years old usually do not need Hib vaccine, but some older children or adults with special health conditions should get it. These conditions include removal of the spleen, sickle cell disease, HIV/AIDS, certain cancers, or other conditions. Persons who have or are going to have cochlear implants also should get Hib vaccine. Ask your doctor or nurse for details.

#### How does Act-HIB<sup>®</sup> work?

Act-HIB<sup>®</sup> causes your (or your child's) body to produce its own protection against Hib bacteria. After receiving a Hib vaccine, your (or your child's) immune system produces antibodies. Antibodies help the body to fight disease. When you are exposed to the Hib bacteria, the antibodies will help to keep you (or your child) from getting sick. As with all vaccines, As with all vaccines, Act-HIB<sup>®</sup> does not protect 100% of people immunized.

#### What are the ingredients in Act-Hib<sup>®</sup>?

Medicinal Ingredients: polyribose ribitol phosphate capsular polysaccharide (PRP) of *Haemophilus influenzae* type b, covalently bound to tetanus protein.

Non-medicinal ingredients: Sodium chloride solution, Sucrose, Tris (hydroxymethyl) aminomethane.

#### Act-HIB<sup>®</sup> comes in the following dosage forms:

Each single dose of Act-HIB<sup>®</sup> is a freeze-dried vaccine to be dissolved in 0.5 mL of the diluent for Act-HIB<sup>®</sup>.

Freeze-dried Act-HIB<sup>®</sup> may also be dissolved in a single dose of QUADRACEL<sup>®</sup> or TRIPACEL<sup>®</sup> if both vaccines are needed.

**Do not use Act-HIB<sup>®</sup> if:**

- You (or your child) have had an allergic reaction to a previous dose of Act-HIB<sup>®</sup> or to any component of Act-HIB<sup>®</sup> or its container.
- You (or your child) have a fever or serious illness. Wait until you are better before taking the vaccine. A person who has had a mild illness (such as a mild cold) may have the vaccine. Ask your doctor, nurse or pharmacist for advice.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you (or your child) take Act-HIB<sup>®</sup>. Talk about any health conditions or problems you or child may have, including if you or your child:**

- **Have a weakened immune system.** The vaccine may provide you (or your child) with a lower level of protection than it does for people with healthy immune systems.
- **Have a coagulation disorder or are on anticoagulant therapy.** Tell the person giving the injection about your/your child's condition. There is a risk of excessive bleeding at the site of injection if it is not done carefully.
- **Are pregnant or breast-feeding.** It is important that you understand the risks and benefits of vaccination. Act-HIB<sup>®</sup> should be given to a pregnant or nursing woman only if it is clearly needed. Tell the person giving the injection if you (or your child) are pregnant or breast-feeding.
- **Have an allergy to any component of the vaccine or the container.**

**Tell your healthcare professional about all the medicines you (or your child) take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with Act-HIB<sup>®</sup>:**

Act-HIB<sup>®</sup> may be mixed with its own diluent, with TRIPACEL<sup>®</sup>, or with QUADRACEL<sup>®</sup>. Act-HIB<sup>®</sup> must not be mixed with other vaccines or medicinal products in the same syringe.

**How to take Act-HIB<sup>®</sup>:**

**Usual dose:**

Each dose is a single injection of 0.5 mL given intramuscularly.

Infants receive one injection at 2, 4, and 6 months of age, followed by a booster at 18 months of age.

If your infant does not start his/her series at 2 months of age, ask your doctor or nurse when the doses of Hib vaccine are needed.

Older children or adults usually receive one injection.

**Overdose:**

If you think you (or your child) have been given too much Act-HIB<sup>®</sup>, contact a health-care professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If a dose is missed, it can be given at any time.

**What are the possible side effects from using Act-HIB®?**

These are not all the possible side effects you may feel when taking Act-HIB®. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warning and Precautions.

A vaccine, like any medicine, may cause serious problems, such as severe allergic reactions. The risk of Act-HIB® causing serious harm is extremely small. The small risks associated with Act-HIB® are much less than the risks associated with getting the diseases against which it protects.

Some children may have mild pain, swelling and redness for a few days at the spot where the needle was given. A very few children may get a mild fever, rash or hives.

Serious side effects are extremely rare.

If you have a troublesome side symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

**Reporting Suspected Side Effects****For the General Public:**

Should you (or your child) experience an adverse event following immunization, please report it to your doctor, nurse, or pharmacist.

Should you require information related to the management of the side effect, please contact your healthcare provider. The Public Health Agency of Canada, Health Canada and Sanofi Pasteur Limited cannot provide medical advice.

**For Health Care Professionals:**

If a patient experiences an adverse event following immunization, please complete the appropriate Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) and send it to your local Health Unit.

**Storage:**

Store the vaccine in a refrigerator at 2° to 8°C (35° to 46°F). Do not freeze. Discard product if it has been exposed to freezing.

Do not use after the expiration date.

Keep out of reach and sight of children.

**If you want more information about Act-HIB®:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; the Sanofi Canada website ([www.sanofi.ca](http://www.sanofi.ca)), or by calling the Sanofi Pasteur Limited Vaccine Information Service at 1-888-621-1146 (no charge) or 416-667-2779 (Toronto area).

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