

New Zealand Consumer Medicine Information

Act-HIB

Haemophilus Influenzae type b Vaccine Conjugated to Tetanus Protein

What is in this leaflet

Read all of this leaflet carefully before your child is vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This vaccine has been prescribed for your child. 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 your doctor or pharmacist.

In this leaflet:

- What Act-HIB is and what it is used for
- Before your child is given Act-HIB
- How Act-HIB is given
- Possible side effects
- Storing Act-HIB
- Further Information

What Act-HIB is and what it is used for

Act-HIB is a vaccine that helps protect your child against *Haemophilus Influenzae* type b infections. This vaccine does not provide protection against infections due to other types of *Haemophilus influenzae* or against cases of meningitis of other origins.

The vaccine may be administered to children from 2 months of age to 5 years of age.

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

When an injection of Act-HIB is given, the immune system (body's natural defences) will protect against *Haemophilus Influenzae* type b infections. However, as with any vaccine, Act-HIB may not protect 100% of vaccinated individuals.

Before your child is given Act-HIB

Who should not receive Act-HIB

- If your child is allergic (hypersensitive) to the active substance or any of the other ingredients of Act-HIB listed in the **Further Information** section.
- If your child has an illness with febrile or acute infection. The vaccination should be postponed until after your child has recovered.

Take special care with Act-HIB

- Tell your doctor before vaccination if your child has a poor immune response (immunosuppression) due to disease or medicines, because your response to the vaccine may be limited.

Use with other vaccines

- Tell your doctor if your child has had any vaccines in the last 4 weeks. Your doctor will advise you if Act-HIB is to be given with another vaccine as a separate injection.

How Act-HIB is given

Act-HIB is administered to your child by your doctor or nurse.

Dosage

Infants:

- Before 6 months of age, administration of 3 successive 0.5mL doses at intervals of one to two months.
- Between 6 and 12 months of age, administration of 2 successive 0.5mL doses at intervals of one to two months.
- This is followed in both cases by a booster dose as per the National Immunisation Schedule.

Children:

- In children over 12 months of age, a single dose of 0.5mL.

Method and/or route(s) of administration

For infants under the age of 12 months, Act-HIB is given as an injection into the upper thigh muscle. In older children who have started walking, the vaccine is usually injected into the upper arm muscle.

Possible Side Effects

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

During clinical studies, the following side effects were reported:

Very common to common:

- Fever
- Irritability
- Injection site reactions such as pain, redness (erythema), swelling, inflammation, hardening of the skin (induration)

Common to uncommon:

- Vomiting
- Crying (uncontrollable or abnormal)
- Fever ($>39^{\circ}\text{C}$)

During post marketing, the following side effects were reported:

Very Rare:

- Swelling (oedema) of lower limbs with symptoms that may include blue or purple coloration of the skin (cyanosis), redness, transient discoloration of the skin (purpura) all symptoms resolving spontaneously without longterm consequences.
- Allergic (hypersensitivity) reactions
- Convulsions (with or without fever)
- Itchy rash (urticaria), rash, itching (pruritis), face swelling (oedema), laryngeal swelling (oedema)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Storing Act-HIB

Keep out of the reach of and sight of children.

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

Do not use Act-HIB after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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.

Further Information

What Act-HIB contains

The active substance is *Haemophilus influenzae* type b polysaccharide: 10µg per 0.5mL dose conjugated to tetanus protein (18-30 µg per 0.5mL dose).

The other ingredients are: trometamol, sucrose, sodium chloride and water for injections.

Act-HIB is a freeze-dried powder for reconstitution with diluent for injection. Following reconstitution, the solution is clear.

Manufacturer

Sanofi Pasteur SA
Lyon, France

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