

Act-HIB®

Haemophilus Type b Conjugate Vaccine (conjugated to tetanus protein)

Consumer Medicine Information

What is in this leaflet

This leaflet answers common questions about Act-HIB.

It does not contain all the available information.

It does not take the place of talking to your doctor.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of your child having Act-HIB against the benefits they expect it will have.

This vaccine has been prescribed for your child. Do not pass it on to others.

If you have any concerns about this vaccine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What Act-HIB 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

When your child must not be given it

Do not have Act-HIB if your child has an allergy to:

- the active substance or any of the other ingredients of Act-HIB listed at the end of this leaflet.
- formaldehyde.

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

Do not have Act-HIB if your child:

- has had a life-threatening reaction after previous administration of this vaccine or a vaccine containing the same substances.
- has an illness with febrile or acute infection. The vaccination should be postponed until after your child has recovered.

Before your child is given it

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.

Tell your doctor if your child has a bleeding disorder.

Tell your doctor if your child has an allergy to latex.

Taking other medicines

Tell your doctor if your child is taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Having 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.

Act-Hib is given as an injection. For children under the age of 24 months, Act-HIB is injected into the upper thigh muscle. In older children who have started walking, the vaccine is usually injected into the upper arm muscle.

How much is given

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.

If you miss a dose

If your child misses a dose, talk to your doctor and arrange another visit as soon as possible.

After having Act-HIB

Things you must do

Keep an updated record of your vaccinations.

Keep follow-up appointments with your doctor or clinic.

It is important for your child to have follow-up doses of Act-HIB at the appropriate times to make sure the vaccines are providing protection against *Haemophilus Influenzae* type b.

Report any side effects to your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if your child does not feel well after having Act-HIB.

Act-HIB may have unwanted side effects in a few people. All medicines, including vaccines, can cause side effects. Sometimes they are serious, most of the time they are not. Your child may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

Your child may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Fever
- Irritability
- Injection site reactions such as pain, redness (erythema), swelling, inflammation, hardening of the skin (induration)
- Vomiting
- Crying (uncontrollable or abnormal)
- Unusual tiredness
- Runny nose
- Diarrhoea

These are the more common side effects of Act-HIB. Mostly these are mild and short-lived.

Tell your doctor immediately if you notice any of the following:

- Extensive limb swelling of the vaccinated limb
- Large injection site reactions (more than 50 mm) such as pain, redness, swelling and/or inflammation or hardening of the skin.
- 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).
- Itchy rash (urticaria), rash generalised, rash, itching (pruritus), face swelling (oedema), laryngeal swelling (oedema)

If any of the following happen, tell your doctor immediately and go to Accident and Emergency at your nearest hospital:

- Allergic (hypersensitivity) reactions, such as itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body.
- Convulsions (with or without fever)

Other side effects not listed above may occur in some patients.

Tell your doctor or pharmacist if you notice anything that is making your child feel unwell.

Storing Act-HIB

Act-HIB is usually stored in the doctor's surgery or clinic, or at the pharmacy. However, if you need to store Act-HIB:

- Keep out of the reach and sight of children.**
- Keep Act-HIB in the original pack until it is time for it to be given.**
- Store in a refrigerator (2°C - 8°C). Do not freeze.**
Freezing destroys the vaccine.

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.

Product description

What it looks like

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

Each pack of Act-HIB contains a single dose vial (containing powder for reconstitution) and 0.5 mL of diluent in a syringe.

Ingredients

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

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

Name and address of sponsor

Australia:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park

NSW 2113, Australia

Telephone: 1800 818 806

New Zealand:

sanofi-aventis new zealand limited

Level 8, 56 Cawley Street

Ellerslie

Auckland

New Zealand

Telephone: 0800 283 684

Date of Preparation

18 March 2020

act-ccds9-cmiv2-18mar20