Act-HIB®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why is my child being given Act-HIB?

Act-HIB is a vaccine that contains the active ingredient Haemophilus type b polysaccharide conjugated to tetanus protein. It is used to protect your child against Haemophilus Influenzae type b infections.

For more information, see Section 1. Why is my child being given Act-HIB? in the full CMI.

2. What should I know before my child is given Act-HIB?

Do not use if your child has ever had an allergic reaction to Act-HIB, formaldehyde or any of the ingredients listed at the end of the CMI.

Talk to your doctor if your child has or has had any other medical conditions or is taking other medicines.

For more information, see Section 2. What should I know before my child is given Act-HIB? in the full CMI.

3. What if my child am taking other medicines?

Some medicines may interfere with Act-HIB and affect how it works.

A list of these medicines is in Section 3. What if my child is taking other medicines? in the full CMI.

4. How Act-HIB is given

- Act-HIB is given by a doctor or nurse as an injection into muscle

More instructions can be found in Section 4. How Act-HIB is given in the full CMI.

5. What should I know after my child is given Act-HIB?

Things you should do	• Keep an updated record of your vaccinations. • Keep follow-up appointments with your doctor or clinic.
Looking after your medicine	• Act-HIB is usually stored in the doctor's surgery or clinic, or at the pharmacy. • Store in a refrigerator (2°C - 8°C). Do not freeze.

For more information, see Section 5. What should I know after my child is given Act-HIB? in the full CMI.

6. Are there any side effects?

Common side effects include local reaction around the injection site (pain, redness, swelling, inflammation, hardening of the skin), fever, irritability, vomiting, crying (uncontrollable or abnormal), unusual tiredness, runny nose, diarrhoea. Serious side effects include 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 of lower limbs with symptoms that may include blue or purple coloration of the skin, redness, transient discoloration of the skin, itchy rash, rash generalised, rash, itching, face swelling, laryngeal swelling, allergic 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).

For more information, including what to do if your child has any side effects, see Section 6. Are there any side effects? in the full CMI.

Act-HIB®

Active ingredient(s): *Haemophilus Type b Conjugate Vaccine (conjugated to tetanus protein)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Act-HIB. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Act-HIB.**

Where to find information in this leaflet:

1. Why is my child being given Act-HIB?
2. What should I know before my child is given Act-HIB?
3. What if my child is taking other medicines?
4. How Act-HIB is given
5. What should I know after my child is given Act-HIB?
6. Are there any side effects?
7. Product details

1. Why is my child being given Act-HIB?

Act-HIB contains the active ingredient Haemophilus type b polysaccharide conjugated to tetanus protein. Act-HIB is a conjugate 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.

2. What should I know before my child is given Act-HIB?

Warnings

Do not use Act-HIB if your child:

- is allergic to the active substance, formaldehyde or any of the ingredients listed at the end of this leaflet.

  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
- 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.

Check with your doctor if your child:

- has a poor immune response (immunosuppression) due to disease or medicines, because their response to the vaccine may be limited.
- has a bleeding disorder
- has an allergy to latex
- has fainted with previous injections. Fainting can occur following, or even before, any needle injections
- has any other medical conditions
- take any medicines for any other condition

After vaccination, your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

3. What if my child is taking other medicines?

Tell your doctor or pharmacist if your child is taking any other medicines, including any medicines, vitamins or supplements 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements your child is taking and if these affect Act-HIB.

4. How Act-HIB is given

How much to use

- 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.

When to use Act-HIB

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 your child misses a dose of Act-HIB

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

If your child received too much Act-HIB

Overdose is most unlikely because your doctor or nurse gives the injections. If you have any concerns, ask your doctor.

5. What should I know after my child is given Act-HIB?

Things you should 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.

Call your doctor straight away if your child:

- does not feel well after having Act-HIB

Remind any doctor, dentist or pharmacist you visit that your child had Act-HIB.

Looking after your child's medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

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.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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.

If your child no longer needs this vaccine or it is out of date, take it to any pharmacy for safe disposal.

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.

6. Are there any side effects?

All medicines can have side effects. If your child does experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• 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	**Speak to your doctor if your child has any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• 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)	**Call your doctor immediately if you notice any of these serious side effects.**

Very serious side effects

Very serious side effects	What to do
• 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)	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects**

Tell your doctor or pharmacist if you notice anything else that may be making your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects your child experienced, you can report side effects

to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems in Australia or in New Zealand at https://pophealth.my.site.com/carmreportnz/s/.

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop giving any medicines to your child.

7. Product details

This medicine is only available with a doctor's prescription.

What Act-HIB contains

Active ingredient (main ingredient)	Haemophilus type b polysaccharide 10mcg conjugated to tetanus protein (18 - 30 mcg per 0.5mL dose)
Other ingredients (inactive ingredients)	• trometamol • sucrose • sodium chloride • water for injections
Potential allergens	Latex

Do not take this medicine if your child is allergic to any of these ingredients.

What Act-HIB 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 single dose vial(s) containing powder for reconstitution and 0.5 mL of diluent in syringe(s) with or without separate needles.

AUST R 130161

Who distributes Act-HIB

Distributed in Australia by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23

300 Barangaroo Avenue

Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

Distributed in New Zealand by:

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics

PO Box 62027

Sylvia Park Auckland 1644

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