

DATA SHEET

NAME OF THE MEDICINE

Act-HIB

Haemophilus Influenzae type b Vaccine Conjugated to Tetanus Protein.

DESCRIPTION

Act-HIB is a freeze-dried powder for reconstitution with diluent for injection. Following reconstitution, the solution is clear. Act-HIB contains the capsular polysaccharide of the *Haemophilus influenzae* type b bacterial strain conjugated to tetanus protein. The polysaccharide consists of polyribosyl ribitol phosphate (PRP).

After reconstitution:

Active ingredients:

Haemophilus influenzae type b polysaccharide (10mcg) conjugated to tetanus protein (18-30mcg).

Excipients:

- Trometamol
- Sucrose
- Sodium Chloride
- Water for injections

No antimicrobial preservative is added.

PHARMACOLOGY

When administered to humans Act-HIB results in an IgG specific anti-PRP response in infants. This response is T-lymphocyte dependent and is characterised by establishment of immunological memory. Antibody response appears to be greater following subcutaneous administration as compared to intramuscular administration.

Although information on the protective efficacy of the Act-HIB from field trials is limited, Act-HIB has been shown to induce antibody levels well above those known to be protective against invasive disease due to *Haemophilus influenzae* type b bacterial strains, in 97-100% vaccinees.

Antibodies generated by Act-HIB are directed against infection caused by the *Haemophilus influenzae* type b bacterial strain only, Act-HIB does not generate antibodies against other organisms, including other strains of *Haemophilus influenzae*.

Study of the functional activity of the anti-PRP antibodies induced by Act-HIB (*Haemophilus influenzae* type b vaccine conjugated tetanus protein) in infants and children, showed opsonization and intracellular phagocytic killing properties.

INDICATIONS

Act-HIB is indicated for use in infants from 2 months to 5 years of age for active immunisation against invasive disease caused by the *Haemophilus influenzae* type b.

The vaccine does not provide protection against infections due to other types of *Haemophilus influenzae*, or against meningitis of other origins.

CONTRAINDICATIONS

Known systemic hypersensitivity to any component of Act-HIB in particular the tetanus protein or a life-threatening reaction after previous administration of the vaccine or a vaccine containing the same substances (See DESCRIPTION).

Vaccination should be postponed in case of febrile or acute disease.

PRECAUTIONS

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following administration of the vaccine.

Under no circumstances should the tetanus protein component contained in Act-HIB be used to replace the routine tetanus vaccination.

As with any vaccine, Act-HIB may not protect 100% of vaccinated individuals.

Do not administer by intravascular injection: ensure that the needles does not penetrate a blood vessel.

As with all injectable vaccines, the vaccine must be administered with caution to individuals with thrombocytopenia or a coagulation disorder since bleeding may occur following an intramuscular administration to these individuals.

The anticipated antibody response may not be obtained in individuals with impaired immune function due to medicines or disease. It is therefore recommended to wait for the end of the treatment for the vaccination. Nevertheless, vaccination of individuals with chronic immunodepression, such as HIV infection, asplenia, or sickle cell disease, is recommended even if the antibody response might be limited.

Experience with native populations (Alaska, native American Indians) generally suggests that response to all conjugated *Haemophilus influenzae* type b vaccines in these populations may

be significantly lower than in Caucasians. The possibility of a lower antibody response in the Australian aboriginal population should be borne in mind.

Cases of *Haemophilus influenzae* type b disease may occur in the weeks after vaccination prior development of an adequate antibody response.

Use in Pregnancy (Category B2)

There is no convincing evidence of risk to the foetus from immunisation of pregnant women using inactivated virus vaccines, bacterial vaccines or toxoids. Data on the use of this vaccine in pregnant women are limited. Therefore, the administration of the vaccine during pregnancy is not recommended.

Use in Lactation

It is not known whether Act-HIB is secreted into human milk. Caution must be exercised when Act-HIB is administered to a nursing mother.

Use in Children

See DOSAGE AND ADMINISTRATION.

Interactions

Act-HIB may be administered concomitantly with other recommended vaccines: Diphtheria, Tetanus, Pertussis and Poliomyelitis, at the same site if combined or at two different sites if associated.

Act-HIB may be administered concomitantly with Hepatitis B or Measles-Mumps-Rubella vaccines at two different sites.

ADVERSE REACTIONS

In line with childhood immunisation schedules, WHO (World Health Organisation) and ACIP (Advisory Committee on Immunisation Practices) recommendations, Act-HIB is rarely administered alone, but often given in association or combination with other concomitant vaccines, such as diphtheria-tetanus-pertussis (whole-cell or acellular) containing vaccines (DTP). Therefore the safety profile of Act-HIB will reflect this concomitant use.

Adverse events presented in this section are listed using MedDRA terminology (system organ classes and terms). Within each system organ class, the adverse events are ranked under headings of frequency (most frequent reactions first), using the following convention:

Very common: $\geq 10\%$

Common: $\geq 1\%$ and $< 10\%$

Uncommon: $\geq 0.1\%$ and $< 1\%$

Rare: $\geq 0.01\%$ and $< 0.1\%$

Very rare: $< 0.01\%$, including isolated reports

DATA FROM CLINICAL STUDIES

During clinical studies with an active monitoring of adverse events, more than 7,000 healthy infants and young children less than 2 years of age were involved and received Act-HIB, almost always in conjunction with whole cell or acellular DTP vaccines.

In controlled studies, when Act-HIB was administered in conjunction with DTP vaccines, the rate and type of subsequent systemic reactions were not different from those seen with DTP administered alone.

Adverse events, possibly related, observed during clinical studies in more than 1% patients after immunisation (i.e. “common” to “very common”) are presented in this section, categorised by frequency. They usually occur soon after the administration of the vaccine (within 6-24 hours), are transient, and have a mild to moderate intensity.

No increase in the incidence or severity of these events was seen with subsequent doses of the primary vaccination series.

The most common reactions occurring after Act-HIB administration were local reactions at the injection site, fever and irritability.

Gastro-Intestinal disorders

- Vomiting: common

General disorders and application site conditions

- General disorders: pyrexia (fever): common (above 39°C: uncommon)
- Application site conditions: Injection site reactions such as pain, erythema, swelling and/or inflammation, induration: common to very common

Psychiatric disorders:

- Irritability: very common
- Crying (uncontrollable or abnormal): uncommon to common

DATA FROM POST-MARKETING EXPERIENCE

The following adverse events were reported during the commercial use of Act-HIB with frequencies of less than 0.01% (very rare). This computation is based on the number of adverse event reports per estimated number of vaccinated patients.

General Disorders and Application Site Conditions:

Oedema of lower limbs: Oedematous reaction affecting one or both limbs may occur following vaccination with Haemophilus Influenzae type b containing vaccines. If this reaction occurs, it does so mainly after primary injections and is observed within the first few hours following vaccination. Associated symptoms may include cyanosis, redness, transient purpura and severe crying. All events resolve spontaneously without sequelae within 24 hours.

Immune System Disorders

Hypersensitivity reactions.

Nervous System Disorders

Convulsions (with or without fever)

Skin and Subcutaneous Tissue Disorders

Urticaria, rash, pruritus, face oedema, laryngeal oedema.

DOSAGE AND ADMINISTRATION

The preferred route of administration for the reconstituted vaccine is the intramuscular route although it may also be given subcutaneously.

The anterolateral thigh is the preferred site for vaccination in infants and children under 12 months of age and the deltoid region is the preferred site for vaccination in older children.

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.

In children over 12 months:

- A single dose of 0.5mL.

Reconstitute one freeze-dried preparation of Act-HIB with one dose of diluent.

Shake vigorously until the freeze-dried preparation is completely dissolved. Shake again immediately before injection.

The reconstituted product must be used immediately after reconstitution.

Once reconstituted, the vaccine must not be mixed with any other vaccine or medicinal product. Therefore, separate injection sites and different syringes should be used in case of concomitant administration.

Product is for single use in one patient only. Discard any residue.

OVERDOSAGE

Not applicable.

PRESENTATION

Vial (containing powder for reconstitution). 0.5 mL diluent in a syringe. 1's.

STORAGE CONDITIONS

Store at 2°C and 8°C (Refrigerate. Do not freeze). Do not use after the expiry date.

MEDICINE CLASSIFICATION

S4 Prescription Only Medicine

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