DOSAGE

The recommended vaccination schedule is three doses of **Quimi-Hib®** starting at 2 months of age, with an interval of 2 months (8 weeks), and in no case less than 1 month. In children who do not start immunization by 2 months of age, it is recommended:

- *Children between 2 and 6 months of age:* three immunizations separated by intervals between 1 and 2 months.

- *Children starting vaccination between 7 and 11 months of age:* only two doses, with an interval of 1 to 2 months.

- *Children starting the scheme from 12 months of age:* a single dose.

- *Booster dose:* to all children who received the immunization schedule in their first year of life, between 15 and 18 months of age, as long as a minimum of 2 months has elapsed since the last dose of the primary schedule.

In all cases, the scheduled dose may be administered up to ± 7 days from the corresponding date.

MODE OF ADMINISTRATION

Quimi-Hib® should be administered intramuscularly in the anterolateral aspect of the thigh, in children under 2 years of age, and at the deltoid level in children over 2 years of age. To obtain the dose of the vaccine (0.5 mL), 0.5 mL of the solution must be extracted and injected.

INTERACTIONS WITH OTHER MEDICATIONS

Quimi-Hib® can be administered at different anatomical sites, with vaccines against diphtheria and tetanus; diphtheria, tetanus and pertussis (DPT); and against hepatitis B. Simultaneous administration at the same anatomical site may be performed by separating each inoculation at a distance greater than 1 inch and using different syringes.

Center for Genetic Engineering and Biotechnology
Distinctive company of Cuban biotechnology which develops, produces, markets and exports innovative products, for key areas of the biomedical, veterinary, agricultural, aquaculture and industrial sectors, for one health. It has a portfolio of research and development (R&D) projects and products, protected by patents. Its more than 30 products marketed in more than 35 countries, include first and only drugs of its kind, to treat diseases that do not have other effective therapeutic solutions. Several of its medicines are inserted into national programs to offer comprehensive health care. We work with social responsibility and in harmony with the environment.

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Quimi-Hib®

CONJUGATE VACCINE AGAINST DISEASES CAUSED BY *HAEMOPHILUS INFLUENZAE* TYPE B (HIB

BETTING ON THE FUTURE

Quimi-Hib®

Conjugate vaccine against diseases caused by *Haemophilus influenzae* type b (Hib)

BETTING ON THE FUTURE

- VACCINE FOR ACTIVE IMMUNIZATION TO CHILDREN FROM 2 MONTHS TO 5 YEARS OF AGE.
- IT IS SAFE, VERY WELL TOLERATED AND POORLY REACTOGENIC.
- ITS PRODUCTION MEETS THE REQUIREMENTS OF THE WORLD HEALTH ORGANIZATION.

PHARMACEUTICAL FORM

Solution for intramuscular injection.

STRENGTH

10 µg/0.5 mL

PRESENTATION

- Case with 25 vials containing a dose of 0.5 mL each.
- Multiple case for 6 cases with 25 vials containing a dose of 0.5 mL each.
- Case with a vial containing a dose of 0.5 mL.
- Multiple cases for 10 cases with a vial containing a dose of 0.5 mL.
- Multiple cases for 10 vials containing a dose of 0.5 mL each.

COMPOSITION

Each dose (0.5 mL) contains 10 µg processed polyribosylribitol phosphate (PRP) conjugated with 26 µg sterile purified tetanus anatoxin; sodium chloride 4 mg; hydrogen disodium phosphate anhydrous 0.56 mg; sodium dihydrogen phosphate dihydrate 0.62 mg; thiomersal 0.025 mg; water for injection c.s. 0.5 mL.

SHELF LIFE AND STORAGE CONDITIONS

Quimi-Hib® is stable during 36 months (3 years), to a temperature from 2 to 8 °C. Do not freeze.

INDICATIONS

Quimi-Hib® is indicated for the active immunization against diseases caused by Haemophilus influenzae type b, for children from 2 months to 5 years of age, such as meningitis, epiglottitis, otitis, pneumonia, among others which may cause disability and death.

CONTRAINDICATIONS

Avoid vaccination in cases of known hypersensitivity to any of the components of the vaccine. Vaccination should be postponed in case of acute febrile illness.

PRECAUTIONS

A 1:1000 adrenaline solution or corticosteroids should be available for immediate use in anaphylactic reactions. Individuals who develop hypersensitivity reactions after administration of one dose of the vaccine should not receive the remaining doses. Administration of the vaccine in children with congenital or acquired immunodeficiency and in those undergoing immunosuppressive therapy, a limited or insufficient immune response may occur.

WARNINGS

Make sure that the needle of the syringe does not penetrate the lumen of any blood vessel. Once the product is administered, discard any remains contained in the vial.

Do not administer intravenously.

UNDESIRABLE EFFECTS

Quimi-Hib® is safe, very well tolerated and little reactogenic. Adverse reactions occur in the first 72 hours after vaccination, are mild and transitory. In controlled clinical studies in infants and older children vaccinated with **Quimi-Hib®**, it was determined that adverse reactions with a frequency greater than 1 % in relation to the total doses administered are: low-grade fever (20.2 %), tenderness in the injection site (2.2 %) and fever greater than 38 °C (1.3 %). Other adverse reactions occur with a much lower frequency (between 0.1 and 0.9 % of the total administered doses): headache (0.8 %), erythema at the injection site (0.8 %), irritability (0.5 %), vomiting (0.5 %), induration at the injection site (0.4 %), rash (0.1 %), drowsiness (0.1 %), diarrhea (0.1 %) and functional impotence (0.1 %). In case of different adverse reactions, the doctor should be consulted.