100 x 120 mm

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For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

Panacea Biotec
Innovation in support of life

Haemophilus Type b Conjugate Vaccine IP

novoHib®

DESCRIPTION

NovoHib® is a bacterial subunit liquid vaccine containing highly purified, non infectious Haemophilus influenzae type b (Hib) capsular polysaccharide polyribosyl ribitol phosphate (PRP) conjugated to the carrier protein of tetanus toxoid. The PRP antigen derived from Hib bacteria is purified through a series of ultra filtration steps, and is covalently bound to the carrier protein of tetanus toxoid (PRP-TT). It is finally adsorbed on aluminium phosphate gel, suspended in isotonic sodium chloride solution to which thiomersal is added as a preservative.

The final product has an appearance of a white or almost white suspension which may sediment at the bottom or side of the container on storage, separating into two phases: a clear supernatant, essentially a PRP-TT free composed of physiological saline, dissolved preservative and aluminium phosphate gel with adsorbed antigen. When shaken, a white or almost white suspension is formed, lasting for some minutes, which is the form in which the product is to be administered.

COMPOSITION

One dose of 0.5 ml contains:

Purified Capsular Polysaccharide (PRP) from *Haemophilus influenzae* type b conjugated to Tetanus Toxoid (20 mcg)	10 mcg
Aluminium (Al^{3+}) content (As aluminium phosphate gel)	0.25 mg
Thiomersal	0.025 mg
Physiological Saline	qs

THERAPEUTIC INDICATION

NovoHib® is indicated for active immunization for the prevention of invasive disease caused by *Haemophilus influenzae* type b in infants from 6 weeks onwards.

PHARMACOLOGICAL PROPERTIES

In a clinical study in India, the immunogenicity of NovoHib® vaccine was evaluated in 6, 10, 14 weeks schedule (3 doses given at 4 weekly intervals) according to the routine vaccination practice in India. Anti-PRP antibody short term protective titer of ≥ 0.15µg/ml was demonstrated in 100% of infants and long term protective titre of ≥ 1µg/ml was demonstrated in 96.8% of infants one month after the completion of the primary vaccination course.

ADMINISTRATION

One dose of 0.5 ml should be injected intramuscularly into anteriolateral aspect of the thigh in infants (For patients with thrombocytopenia or bleeding disorders the injection should be given subcutaneously). Do not inject intravenously.

USE IN SPECIAL POPULATION

As NovoHib® is not intended for use in adult, information on the safety of the vaccine when used during pregnancy or lactation is not available.

IMMUNIZATION SCHEDULE

In general, a three dose primary series is given at the same time as the primary series of DTP. The first dose is given at 6 weeks of age or older and second and third doses are given at 4-8 weeks interval along with DTP. A booster dose is recommended to be administered between 12 and 18 months.

NovoHib® vaccine can be given safely and effectively at the same time as DTP, Measles, Polio vaccines (OPV or IPV), Hepatitis B, Yellow fever vaccine and Vitamin A supplementation. NovoHib® vaccine should be given as a separate injection at the same time as other vaccines; it should be administered at a different site. It should not be mixed in the vial or syringe with any other vaccine.

SIDE EFFECTS

In controlled clinical studies, signs and symptoms were actively monitored and recorded following administration of the vaccine.

The most frequent local symptom was tenderness reported within the first 72 hours at injection site which resolved spontaneously. Other local solicited symptoms reported were mild to moderate swelling, pain and redness at the injection site.

The general solicited symptoms which have been reported within the first 72 hours were fever, loss of appetite, restlessness, vomiting, diarrhoea and unusual crying. The most frequent general solicited event was fever. These general solicited symptoms have been reported when Hib vaccine is administered concomitantly with other vaccines.

In case you experience any undesirable effect following intake of this medication please feel free to contact us at any of the following contact details: e-mail id: pvg@panaceabiotec.com; Fax no.: +91-11-41679069; M. No. +91-9650138282.

OVERDOSE

No case of overdose has been reported.

CONTRAINDICATIONS

NovoHib® should not be administered to subjects with known hypersensitivity to any component of the vaccine, or to subjects that have shown any signs of hypersensitivity after previous administration of Hib vaccine.

As with other vaccines, the administration of NovoHib® should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor non-febrile infection, however, is not a contraindication to vaccination.

NovoHib® should under no circumstances be administered intravenously.

IMMUNE DEFICIENCY

HIV positive children, both asymptomatic and symptomatic, should not be considered as contraindication for NovoHib® vaccination.

SPECIAL WARNING AND PRECAUTION

As with all injectable vaccines, supervision and medical treatment should be readily available in case of any anaphylactic reaction following vaccination.

Excretion of capsular polysaccharide antigen in the urine has been reported following Hib vaccination hence antigen detection may not have a diagnostic value in suspected Hib patients within 1-2 weeks of vaccination.

DRUG INTERACTION

NovoHib® can be administered simultaneously at separate sites or in any temporal relationship with other paediatric vaccines if this fits conveniently in the immunization scheme.

As with other intramuscular injections, use with caution in patients on anticoagulant therapy. Immunosuppressive therapies, including irradiations, antimetabolites, alkylating agents, cytotoxic drugs and corticosteroids (used in greater than physiologic doses), may reduce the immune response to vaccines. Short-term (<2 weeks) corticosteroid therapy or intra-articular, bursal, or tendon injections with corticosteroids would not be immunosuppressive.

PRESENTATION

Single dose prefilled syringe containing 0.5 ml vaccine with LuerLok & PRTC (plastic rigid tip cap).

SHELF LIFE

36 months from the date of manufacturing when stored at 5ºC ± 3ºC.

STORAGE

The NovoHib® vaccine should be stored and transported at temperature between 5°C±3°C until the expiry date indicated on the label.

IT MUST NOT BE FROZEN.

PREPARATION FOR INJECTION

Remove the prefilled syringe from the blister pack. Holding the syringe barrel, remove the PRTC from the tip of syringe. The PRTC design makes the tip cap easy to open and promote aseptic technique by reducing risk of syringe tip contamination during cap removal. Attach the needle to the LuerLok syringe. LuerLok Adaptor design helps in maintaining "Needle Integrity" by not allowing needle to touch any other material.

In the unusual event of the piston rod becoming loose or falling off, screw it clockwise into the plunger in order to secure it.

Each prefilled syringe should be used only once.

The peel-off label on the barrel of the syringe is to be pasted on the vaccinee's vaccination card for future reference.

Manufactured by :
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PMPISO3002