

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Product Name: *Haemophilus influenzae* Type b Conjugate Vaccine IP

Brand Name : NovoHIB®

Strength: One pediatric dose is 0.5 ml

Pharmaceutical Form: Injectable Vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 0.5 ml contains:

Component	Quantity
Purified Capsular Polysaccharide (PRP) from <i>Haemophilus influenzae</i> type b conjugated to tetanus toxoid 20-40 mcg	10 mcg
Aluminium (Al ³⁺) content (As Aluminium Phosphate Gel)	0.25 mg
Thiomersal	0.025 mg
Physiological saline	q.s.

3. PHARMACEUTICAL/ DOSAGE FORM

Injectable Vaccine

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

NovoHIB® is indicated for active immunization for the prevention of invasive disease caused by *Haemophilus influenzae* type b.

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4.2 Posology and method of 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.

4.3 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.

4.4 Special warnings and precautions for use

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.

4.5 Interaction with other medicinal products and other forms of Interaction

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.

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4.6 Pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

As NovoHIB[®] is not intended for use in adult, information on effect on driving skills or the capability to operate machines is not available.

4.8 Undesirable 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.

4.9 Overdose

Not Applicable, as NovoHIB[®] vaccine is to be administered as per the pediatric immunization schedule under the direct supervision of physicians.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic 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 ≥ 0.15 $\mu\text{g/ml}$ was demonstrated in 100% of infants and long term protective titer of

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≥1µg/ml was demonstrated in 96.8% of infants one month after the completion of the primary vaccination course.

5.2 Pharmacokinetic properties

Not Applicable

5.3 Preclinical safety data

The preclinical studies on the Hib-TT component (manufactured by CDAP conjugating agent) were carried out by following GLP accredited Laboratory, Jai Research Foundation, Department of Toxicology, Valvada, Distt.- Valsad, Gujarat, India

1. Single dose toxicity and local tolerance study of *Haemophilus influenzae* type b conjugate vaccine (Hib-TT conjugate vaccine) in New Zealand White Rabbits by Intramuscular route.
2. Single dose toxicity of *Haemophilus influenzae* type b conjugate vaccine (Hib-TT conjugate vaccine) in Balb/c mice by Intramuscular route.
3. Repeat Dose Toxicity Study of *Haemophilus Influenzae* Type b Conjugate Vaccine (HIB-TT Conjugate Vaccine) in Balb/c Mice by Intramuscular Route (N + 1 = 4 Schedule).
4. Repeat Dose Toxicity Study of *Haemophilus Influenzae* Type b Conjugate Vaccine (HIB-TT Conjugate Vaccine) in New Zealand White Rabbits By Intramuscular Route (N + 1 = 4 Schedule).

The toxicology studies have demonstrated the safety of the Hib-TT conjugated by CDAP in standalone product (Hib-TT Vaccine).

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

- Sodium chloride
- Thiomersal
- Aluminium phosphate gel
- Water for injection

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6.2 Incompatibilities

Not Applicable

6.3 Shelf life

The shelf-life of NovoHIB[®] vaccine is 36 months when stored at 5°C ± 3°C.

6.4 Special precautions for storage

NovoHIB[®] vaccine should be stored and transported at 5 ± 3°C until the expiry date indicated on the label.

It must not be frozen.

6.5 Nature and contents of container

NovoHIB[®] vaccine is to be filled in tubular, colourless glass vials and stoppered with bromo butyl rubber closures and finally sealed with flip off aluminium seals as well as in Pre-filled syringe of USP type 1 glass stoppered with plunger stopper in below mentioned presentations:

Vial Presentations:

Single dose vial containing 0.5 ml vaccine.

Multi-dose (5 doses) vial containing 2.5 ml vaccine

Multi-dose (10 doses) vial containing 5.0 ml vaccine

Prefilled Syringe Presentation:

Single dose Prefilled Syringe containing 0.5 ml vaccine.

6.6 Special precautions for disposal

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.

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7. MARKETING AUTHORISATION HOLDER

Panacea Biotec Ltd.
Malpur, Baddi, Distt Solan,
Himachal Pradesh – 173205, India
Tel. : 01795-674036
E-mail : corporate@panaceabiotec.com
Website: <https://www.panaceabiotec.com>

8. MARKETING AUTHORISATION NUMBER(S)

Manufacturing License no: MB/07/632.

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

- Date of first authorization: September 29, 2007
- Renewal of the authorization: granted on September 29, 2012 valid up to 28.09.2017
- Renewal of the authorization: granted on September 29, 2017 valid up to 28.09.2022.
- Retained upto September 28, 2027