HIBERIX

SCHEDULING STATUS:

S2

PROPRIETARY NAME AND DOSAGE FORM:

HIBERIX®

Haemophilus influenzae type b conjugate vaccine.

Powder and diluent for solution for injection.

COMPOSITION:

Each 0,5 ml dose contains 10 µg *Haemophilus influenzae* type b capsular polysaccharide (PRP) conjugated to tetanus toxoid.

Excipients:

The vaccine contains10,08 mg lactose per 0,5 ml dose

The diluent is a sterile saline solution.

PHARMACOLOGICAL CLASSIFICATION:

A 30.2 Biologicals, antigens

PHARMACOLOGICAL ACTION:

HIBERIX is a lyophilised vaccine of purified polyribosyl-ribitol-phosphate capsular polysaccharide (PRP) of Hib, covalently bound to 20-40 µg of tetanus toxoid which has been shown to induce antibodies to the capsular polysaccharide of *Haemophilus influenzae* type b.

INDICATIONS:

HIBERIX is indicated for active immunisation of all infants from the age of 6 weeks against disease caused by *Haemophilus influenzae* type b (Hib).

HIBERIX does not protect against disease due to other types of *Haemophilus influenzae* nor against other organisms that cause meningitis or septic disease.

CONTRA-INDICATIONS:

HIBERIX should not be administered to subjects with known hypersensitivity to any component of the vaccine or to subjects having shown signs of hypersensitivity after previous administration of Hib vaccines.

WARNINGS AND SPECIAL PRECAUTIONS:

The administration of HIBERIX should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection, however, is not a contra-indication for vaccination.

Human Immunodeficiency Virus (HIV) infection is not considered as a contra-indication for HIBERIX.

Although limited immune response to the tetanus toxoid component may occur, vaccination with HIBERIX alone does not substitute for routine tetanus vaccination.

HIBERIX should under no circumstances be administered intravenously.

The potential risk of apnoea and the need for respiratory monitoring for 48-72 hours should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important to have procedures in place to avoid injuries from faints.

Appropriate medical treatment should always be readily available including adrenaline in case of a rare anaphylactic event following the administration of the vaccine. For this reason, the vaccinee should remain under medical supervision for 30 minutes after immunisation.

Excretion of capsular polysaccharide antigen in the urine has been described following receipt of Hib vaccines and therefore antigen detection may not have a diagnostic value in suspected Hib disease within 1-2 weeks of vaccination.

INTERACTIONS:

HIBERIX can be administered either simultaneously or at any time before or after a different inactivated or live vaccine.

Other injectable vaccines should be administered at different injection sites.

It may be expected that in patients receiving immunosupressive therapy or patients with immunodeficiency, an adequate response may not be achieved.

PREGNANCY AND LACTATION:

Safety and efficacy have not been established.

DOSAGE AND DIRECTIONS FOR USE:

The primary vaccination schedule consists of three doses at 6-, 10- and 14- weeks of age. To ensure a long term protection, a booster dose is recommended in the second year of life.

Method of Administration:

The reconstituted vaccine is for **intramuscular** injection in the deltoid region. However, in patients with thrombocytopenia or bleeding disorders, the vaccine should be administered subcutaneously.

HIBERIX should under no circumstances be administered intravenously.

Use and Handling:

The diluent and reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to administration. In the event of either being observed, discard the diluent or reconstituted vaccine.

Any unused product or waste material should be disposed of in accordance with local requirements.

Instruction for reconstitution of the vaccine with diluents presented in vials:

HIBERIX must be reconstituted by adding the entire contents of the supplied vial of diluent to the vial containing the powder. After the addition of the diluent to the powder, the mixture should be well shaken until the powder is completely dissolved in the diluent. The reconstituted vaccine is a clear and colourless solution.

After reconstitution, the vaccine should be used promptly.

Withdraw the entire contents of the vial.

A new needle should be used to administer the vaccine.

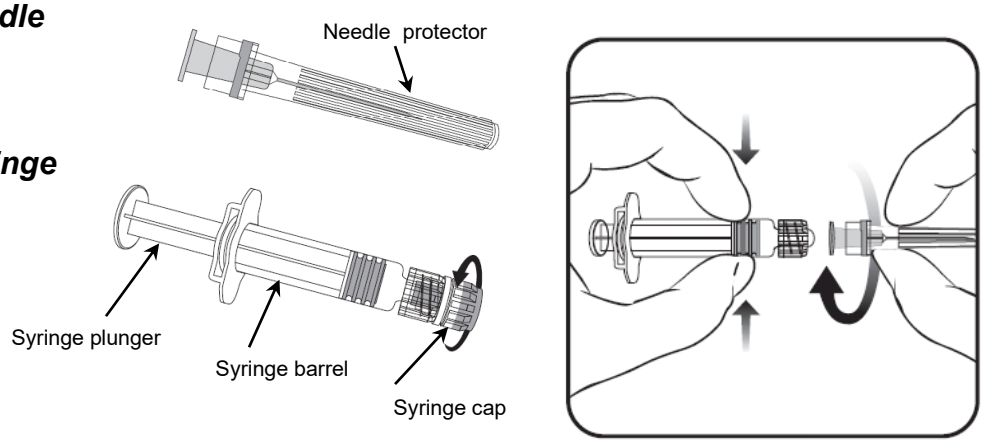
Instructions for reconstitution of the vaccine with the diluents presented in a prefilled syringe:

HIBERIX must be reconstituted by adding the entire content of the pre-filled syringe of diluent to the vial containing the powder.

To attach the needle to the syringe, refer to the below drawing. However, the syringe provided with HIBERIX might be slightly different than the syringe described in the drawing.

Needle

Syringe



1. Holding the syringe barrel in one hand (avoid holding the syringe plunger), unscrew the syringe cap by twisting it anticlockwise.
2. To attach the needle to the syringe, twist the needle clockwise into the syringe until you feel it lock. (see picture)
3. Remove the needle protector, which on occasion can be a little stiff.

Add the diluent to the powder. After the addition of the diluent to the powder, the mixture should be well shaken until the powder is completely dissolved in the diluent. The reconstituted vaccine is a clear and colourless solution.

After reconstitution, the vaccine should be used promptly.

A new needle should be used to administer the vaccine.

Withdraw the entire contents of the vial.

SIDE EFFECTS:

Clinical trial data:

The adverse reactions observed in a large controlled safety clinical trial following vaccination with HIBERIX are listed below:

Undesirable effects reported are listed according to the following frequency:

Very common ≥ 1/10

Common ≥ 1/100 to < 1/10

Uncommon ≥ 1/1 000 to < 1/100

Rare ≥1/10 000 to < 1/1 000

Very rare < 1/10 000

Not known (cannot be estimated from the available data).

Metabolism and nutritional disorders:

Very common: loss of appetite

Psychiatric disorders:

Very common: unusual crying, restlessness

Gastrointestinal disorders:

Very common: diarrhoea

Common: vomiting

General disorders and administration site conditions:

Very common: fever, redness at the injection site

Common: pain and swelling at the injection site.

Post-marketing data:

Immune system disorders: allergic reactions (including anaphylactic and anaphylactoid reactions), angioedema

Nervous system disorders: hypotonic-hyporesponsive episode, convulsion (with or without fever), syncope or vasovagal responses to injection, somnolence

Respiratory, thoracic and mediastinal disorders: apnoea

Skin and subcutaneous tissue disorders: urticaria, rash

General disorders and administration site conditions: extensive swelling of vaccinated limb, injection site induration.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF TREATMENT:

See SIDE EFFECTS.

Treatment is symptomatic and supportive.

IDENTIFICATION:

Vaccine: White cake or powder contained in a glass vial sealed with a rubber stopper.

Diluent: Clear, colourless, odourless liquid, free from visible particles.

Reconstituted solution: Clear, colourless liquid free from visible particles.

PRESENTATION:

The lyophilised vaccine is presented in a 3 ml clear glass vial.

The sterile diluent (saline) is presented in a 3 ml clear glass vial or a pre-filled syringe.

STORAGE INSTRUCTIONS:

Store the lyophilised vaccine between +2 °C and +8 °C and protect from light.

Store the diluent below 25 °C or between +2 °C and +8 °C. DO NOT FREEZE.

Discard any unused reconstituted solution.

Keep out of the reach of children.

REGISTRATION NUMBER:

32/30.1/0349

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

GlaxoSmithKline South Africa (Pty) Ltd

39 Hawkins Avenue

Epping Industria 1, 7460

DATE OF PUBLICATION OF THE PACKAGE INSERT:

3 October 2013

GDS-7

Namibia: Reg No 04/30.1/0891 NS1

SKEDULERINGSTATUS:

S2

EIENDOMSNAAM EN DOSEERVORM:

HIBERIX

Haemophilus influenzae tipe b konjugaatvaksien.

Poeier en verdunningsmiddel vir oplossing vir inspuiting.

SAMESTELLING:

Elke 0,5 ml dosis bevat 10 µg *Haemophilus influenzae* tipe b kapsulêre polisakkaried (PRP) gekonjugeer met tetanustoksoïed.

Mengmiddels:

Die vaksien bevat 10,08 mg laktose per 0,5 ml dosis.

Die verdunningsmiddel is 'n steriele soutoplossing.

FARMAKOLOGIESE KLASSIFIKASIE:

A 30.2 Biologiese middels, antigene

FARMAKOLOGIESE WERKING:

HIBERIX is 'n geliofiliseerde vaksien van gesuiwerde poliribosiel-ribitol-fosfaat kapsulêre polisakkaried (PRP) van Hib, kovalent gebonde aan 20-40 µg tetanustoksoïed, waar daar aangedui kon word dat dit teenliggaampies teen die kapsulêre polisakkaried van *Haemophilus influenzae* tipe b induseer.

INDIKASIES:

HIBERIX word aangedui vir aktiewe immunisasie van alle suigelinge vanaf die ouderdom van 6 weke teen siekte wat deur *Haemophilus influenzae* tipe b (Hib), veroorsaak word.

HIBERIX beskerm nie teen siekte wat die gevolg is van ander tipes *Haemophilus influenzae* of teen ander organismes wat meningitis of septiese siekte veroorsaak nie.

KONTRA-INDIKASIES:

HIBERIX behoort nie aan persone met bekende hipersensitiwiteit teenoor enige komponent van die vaksien, of persone wat tekens van hipersensitiwiteit na vorige toediening van Hib-vaksiene getoon het, toegedien te word nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:

Die toediening van HIBERIX moet uitgestel word by persone wat aan akute ernstige koorsige siekte ly. Die teenwoordigheid van 'n minder belangrike infeksie is egter nie 'n teenaanduiding vir vaksinering nie.

Mensimmuungebrekvirus-infeksie (MIV-infeksie) word nie as 'n kontra-indikasie vir HIBERIX beskou nie.

Alhoewel beperkte immuunreaksie teen die tetanustoksoïedkomponent mag voorkom, is vaksinering met HIBERIX op sy eie nie 'n plaasvervanger vir roetine tetanusvaksinering nie.

HIBERIX behoort onder geen omstandighede intraveneus toegedien te word nie.

Die potensiële risiko van apnee en die behoefte vir respiratoriese monitering vir 48-72 uur behoort oorweeg te word wanneer die primêre immunisasiereeks aan baie premature suigelinge (gebore ≤ 28 weke van gestasie), en veral vir dié met 'n vorige geskiedenis van respiratoriese onrypheid, toegedien word. Omdat die voordeel van

vaksinering in hierdie groep suigelinge hoog is, behoort vaksinering nie weerhou of vertraag te word nie.

Sinkopee (floute) kan voorkom na, of selfs voor, enige vaksinering as 'n psigogeniese respons op die inspuiting met 'n naald. Dit is belangrik om prosedures in plek te hê om beserings weens floutes te kan vermy.

Toepaslike mediese behandeling, insluitend adrenalien, moet altyd vrylik beskikbaar wees in geval van 'n seldsame anafilaktiese insident na die toediening van die vaksien.

Vir hierdie rede behoort die persoon wat gevaksineer is, vir 30 minute na immunisasie onder mediese toesig te bly.

Uitskeiding van kapsulêre polisakkariedantigeen in die urien is na ontvangs van Hib-vaksiene beskryf en antigeenbepaling mag dus binne 1-2 weke na vaksinering, geen diagnostiese waarde in vermoede Hib-siekte hê nie.

INTERAKSIES:

HIBERIX kan óf gelyktydig, óf op enige tyd voor, of na, 'n ander geïnaktiveerde of lewende vaksien toegedien word.

Ander inspuitbare vaksiene behoort op verskillende inspuitingsplekke toegedien te word.

Daar kan verwag word dat 'n toereikende reaksie by pasiënte wat immuunonderdrukkende terapie ontvang, of pasiënte met immuungebrek, moontlik nie verkry sal word nie.

SWANGERSKAP EN LAKTASIE:

Veiligheid en doeltreffendheid is nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Die primêre vaksineringskedule bestaan uit drie dosisse op die ouderdom van 6-, 10- en 14-weke. Om langtermyn beskerming te verseker, word 'n versterkerdosis in die tweede lewensjaar aanbeveel.

Metode van Toediening:

Die hersaamgestelde vaksien is slegs vir **intramuskulêre** inspuiting in die deltoïed gebied bedoel. By pasiënte met trombositopenie of bloedingsiekte, behoort die vaksien egter onderhuids toegedien te word.

HIBERIX behoort onder geen omstandighede intraveneus toegedien te word nie.

Gebruik en Hantering:

Die verdunningsmiddel en hersaamgestelde vaksien behoort visueel vir enige vreemde partikels en of variasie in die fisiese aspekte ondersoek te word voor toediening. In 'n geval dat iedereen waargeneem word, moet die verdunningsmiddel of hersaamgestelde vaksien weggegooi word.

Enige ongebruikte produk of afvalmateriaal moet weggedoen word in ooreenstemming met plaaslike vereisdes.

***Instruksies vir hersamestelling van die vaksien met verdunningsmiddels wat in flessies aangebied word*:**

HIBERIX moet hersaamgestel word deur die hele inhoud van die verskafte flessie verdunningsmiddel by die flessie wat die poeier bevat, te voeg. Na byvoeging van die verdunningsmiddel by die poeier, behoort die mengsel goed geskud te word totdat die poeier volkome in die verdunningsmiddel opgelos is. Die hersaamgestelde vaksien is 'n helder en kleurlose oplossing.

Na hersamestelling behoort die vaksien dadelik gebruik te word.

Onttrek die hele inhoud van die flessie.

'n Nuwe naald moet vir toediening van die vaksien gebruik word.

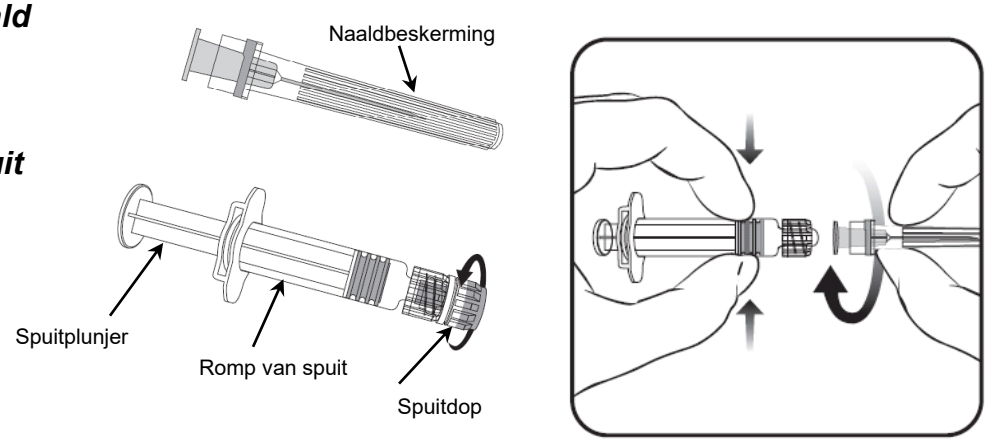
***Instruksies vir hersamestelling van die vaksien met verdunningsmiddels wat in 'n voorafgevulde spuit aangebied word*:**

HIBERIX moet hersaamgestel word deur die hele inhoud van die voorafgevulde spuit van verdunningsmiddel by die flessie wat die poeier bevat, te voeg.

Om die naald aan die spuit te heg, verwys na onderstaande prentjie. Die spuit wat saam met HIBERIX verskaf word mag egter effens verskil van die spuit wat in die prentjie beskryf word.

Naald

Spuit



1. Terwyl die romp van die spuit met een hand vasgehou word (moenie die spuitplunjer vashou nie), moet die spuitdop afgeskroef word deur dit antikloksgewys te draai.
2. Om die naald aan die spuit te koppel, moet die naald kloksgewys op die spuit gedraai word totdat jy kan voel dat dit gesluit het. (sien prentjie)
3. Verwyder die naaldbeskerming wat soms effens styf kan wees.

Voeg die verdunningsmiddel by die poeier. Na byvoeging van die verdunningsmiddel aan die poeier, behoort die mengsel goed geskud te word totdat die poeier volkome in die verdunningsmiddel opgelos is. Die hersaamgestelde vaksien is 'n helder en kleurlose oplossing.

Na hersamestelling behoort die vaksien so gou as moontlik gebruik te word.

'n Nuwe naald moet gebruik word om die vaksien toe te dien.

Onttrek die hele inhoud van die flessie.

NEWE-EFFEKTE:

Data van kliniese studies:

Die nadelige reaksies wat in 'n groot beheerde kliniese veiligheidstudie na vaksinering met HIBERIX waargeneem is, word hierna gelys:

Ongewenste effekte wat aangemeld is, word volgens die volgende frekwensies gelys:

Baie algemeen: ≥ 1/10

Algemeen: ≥ 1/100 tot < 1/10

Ongewoon: ≥ 1/1 000 tot < 1/100

Seldsaam: ≥ 1/10 000 tot < 1/1 000

Baie seldsaam: < 1/10 000

Nie bekend nie (kan nie van die beskikbare data beraam word nie).

***Metabolisme en voedingversteurings*:**

Baie algemeen: verlies aan aptyt

***Psigiatriese versteurings*:**

Baie algemeen: ongewone huil, rusteloosheid

***Gastroïntestinale versteurings*:**

Baie algemeen: diarree

Algemeen: braking

***Algemene versteurings en toestande by die toedieningsplek*:**

Baie algemeen: koors, rooiheid by die inspuitingsplek

Algemeen: pyn en swelling by die inspuitingsplek.

Nabemarkingsdata:

Immuunsisteemversteurings: allergiese reaksies (insluitend anafilaktiese en anafilaktoïede reaksies), angio-edeem

***Senusisteemversteurings*:** hipotoniese-hiporesponsiewe episode, konvulsie (met, of sonder koors), sinkopee of vasovagale reaksies op inspuiting, lomerigheid

***Respiratoriese, torakale en mediastinale versteurings*:** apnee

***Vel- en onderhuidse weefselversteurings*:** urtikarie, veluitslag

***Algemene versteurings en toestande by die toedieningsplek*:** uitgebreide swelling van die ingespuite ledemaat, indurasie by die inspuitingsplek.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Sien NEWE-EFFEKTE.

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

Vaksien: Wit koekie of poeier in ’n glasflessie wat met ’n rubberprop verseël is.

Verdunningsmiddel: Helder, kleurlose, reuklose vloeistof, vry van sigbare partikels.

Hersaamgestelde oplossing: Helder, kleurlose vloeistof, vry van sigbare partikels.

AANBIEDING:

Die geliofiliseerde vaksien word in ’n 3 ml helder glasflessie aangebied.

Die steriele verdunningsmiddel (soutoplossing) word in ’n 3 ml helder glasflessie of ’n voorafgevulde spuit, aangebied.

BEWARINGSINSTRUKSIES:

Bewaar die geliofiliseerde vaksien tussen +2 °C en +8 °C en beskerm teen lig.

Bewaar die verdunningsmiddel onder 25 °C of tussen +2 °C en +8 °C. MOENIE VRIES NIE.

Raak van enige ongebruikte hersaamgestelde oplossing ontslae.

Hou buite bereik van kinders.

REGISTRASIENOMMER:

32/30.1/0349

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:

GlaxoSmithKline South Africa (Edms) Bpk

Hawkinslaan 39

Epping Industrie 1, 7460

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:

3 Oktober 2013

HIBERIX is ’n geregistreerde handelsmerk van die **GSK**-maatskappyegroep