# Patient Information Leaflet

**SCHEDULING STATUS:**

S2

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:**

**HIBERIX**

*Haemophilus influenzae* type b conjugate vaccine.

Powder and diluent for solution for injection.

**Read all of this leaflet carefully before your child is vaccinated.**

HIBERIX is not for self-medication, and must be administered by a healthcare professional.

Keep this leaflet. You may need to read it again.

If you have any further questions, please ask your doctor or pharmacist.

HIBERIX has been prescribed for your child only. Do not pass it on to others; it may harm them even if their symptoms are the same.

**WHAT HIBERIX CONTAINS:**

Each dose of this vaccine contains 10 µg *Haemophilus influenzae* type b polyribosyl-ribitol-phosphate capsular polysaccharide bound to approximately 30 µg of tetanus toxoid.

The other ingredients are 10,08 mg lactose per 0,5 ml dose and sterile saline solution.

**WHAT HIBERIX IS USED FOR:**

HIBERIX is a vaccine used to protect children from 6 weeks of age against disease caused by *Haemophilus influenzae* type b.

The vaccine works by causing your child's body to make its own protection (antibodies) which will protect your child against the disease.

As with all vaccines, HIBERIX may not fully protect all children who are vaccinated.

HIBERIX will only protect against infections caused by the *Haemophilus influenzae* type b for which the vaccine has been developed.

Children with a weakened immune system (such as due to HIV infection) may not get the full benefit from HIBERIX.

**BEFORE YOU ARE GIVEN HIBERIX:**

**Your child should not be given HIBERIX if:**

- your child has previously had an allergic reaction to HIBERIX, or to any ingredient contained in this vaccine. The active substance and other ingredients in HIBERIX are listed at the beginning of this leaflet. Signs of an allergic reaction may include itchy skin, rash, shortness of breath and swelling of the face or tongue.

If the above has happened to your child, you should tell your doctor or healthcare professional before being given the injection.

**Special care should be taken with HIBERIX:**

- if your child has a severe infection with a high temperature. In these cases, the vaccination will be postponed until recovery. A minor infection such as a cold should not be a problem, but talk to your doctor first

- if your child has breathing difficulties, please contact your doctor. This may be more common in the first three days following vaccination if your child is born prematurely (before or at 28 weeks of pregnancy).

Fainting can occur following, or even before, any needle injection, therefore tell your doctor or nurse if your child fainted with a previous injection.

**Taking other medicines with HIBERIX:**

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of HIBERIX with these medicines may cause undesirable interactions. Please consult your doctor for advice.

In particular, tell your doctor or pharmacist if your child is taking any medicines or has an infection that affects the immune system (the body's natural defence system) since your child may not get the full benefit from HIBERIX.

HIBERIX can be given at the same time as other childhood vaccines. A different place for the injection will be used for each vaccine.

**HOW TO RECEIVE HIBERIX:**

HIBERIX is usually given as three separate injections at 6-, 10- and 14-weeks of age.

If additional doses (boosters) are necessary, the nurse or doctor will tell you.

HIBERIX is usually injected into a muscle; however it may be injected under the skin in patients with a blood disorder.

The vaccine must NOT be injected into a vein.

**If your child misses a dose of HIBERIX:**

If your child misses a scheduled dose, it is important that you make another appointment as soon as you can. If you do not finish the complete vaccination course of

three injections, your child may not get the best response and protection from the vaccine.

**POSSIBLE SIDE EFFECTS:**

HIBERIX can have side effects.

Not all side effects reported for HIBERIX are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using HIBERIX, please consult your doctor , pharmacist or other healthcare professional for advice.

**Allergic reactions:**

As with all injectable vaccines, your child may experience an allergic reaction. Allergic reactions are very rare.

The signs of an allergic reaction may include:

- skin rashes that may be itchy or blister
- swelling of the eyes and face
- difficulty in breathing or swallowing.

These signs usually start very soon after the injection has been given. Take your child to see a doctor straight away if they happen after leaving the clinic.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following serious side effects:

- collapse, loss of consciousness, lack of awareness
- fits.

**Other side effects include:**

- pain, redness and swelling at the injection site
- high temperature, loss of appetite
- feeling restless
- vomiting (being sick), diarrhoea
- unusual crying.

**The following side effects may also occur**:

- fainting due to injection
- feeling sleepy
- temporarily stopping breathing
- hives, rash
- large swelling of the injected limb
- hard lump at the injection site.

If any of these side effects get serious, please tell your doctor or pharmacist.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**STORING AND DISPOSING OF HIBERIX:**

Keep all medicines out of the reach and sight of children.

Store at +2 °C to +8 °C (in a refrigerator).

DO NOT FREEZE. Discard if vaccine has been frozen.

Store in the original package in order to protect from light.

Do not use after the expiry date stated on the label and packaging. The expiry date refers to the last day of that month.

Discard any unused reconstituted solution.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**PRESENTATION OF HIBERIX:**

The vaccine is presented in a 3 ml clear glass vial sealed with a rubber stopper.

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

**IDENTIFICATION OF HIBERIX:**

The vaccine is a white cake or powder, which after mixing with the diluent is a clear, colourless liquid free from visible particles.

The diluent is a clear, colourless, odourless liquid, free from visible particles.

The reconstituted solution is a clear, colourless liquid free from visible particles.

**REGISTRATION NUMBER:**

32/30.1/0349

**NAME AND ADDRESS OF REGISTRATION HOLDER:**

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# Pasiëntinligtingsbrosjure

**SKEDULERINGSTATUS:**

S2

**EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM:**

**HIBERIX®**

*Haemophilus influenzae* tipe b konjugaatvaksien.

Poeier en verdunningsmiddel vir oplossing vir inspuiting.

**Lees hierdie hele brosjure versigtig alvorens jou kind gevaksineer word.**

HIBERIX is nie vir selfmedikasie bedoel nie, en moet deur 'n gesondheidsorgkundige toegedien word.

Bewaar hierdie brosjure. Jy mag dit weer moet lees.

As jy enige addisionele vrae het, vra asseblief jou dokter of apteker.

HIBERIX is alleenlik vir jou kind voorgeskryf. Moenie dit vir ander persone gee nie; dit kan hulle skade aandoen, al is hulle simptome dieselfde.

**WAT HIBERIX BEVAT:**

Elke dosis van hierdie vaksien bevat 10 µg *Haemophilus influenzae* tipe b poliribosiel-ribitol-fosfaat kapsulêre polisakkaried gebonde aan ongeveer 30 µg tetanustoksoïed.

Die ander bestanddele is 10,08 mg laktose per 0,5 ml dosis en steriele soutoplossing.

**WAARVOOR HIBERIX GEBRUIK WORD:**

HIBERIX is ’n vaksien wat gebruik word om kinders vanaf die ouderdom van 6 weke teen siekte wat deur *Haemophilus influenzae* tipe b veroorsaak word, te beskerm.

Die vaksien werk deur te veroorsaak dat jou kind se liggaam sy eie beskerming (teenliggaampies) maak, wat jou kind teen die siekte sal beskerm.

Soos met alle vaksiene, mag HIBERIX nie alle kinders wat gevaksineer word, ten volle beskerm nie.

HIBERIX sal slegs teen infeksies veroorsaak deur *Haemophilus influenzae* tipe b waarvoor die vaksien ontwikkel is, beskerm.

Kinders met ’n verswakte immuunsisteem (byvoorbeeld as gevolg van MIV-infeksie) mag nie die volle voordeel van HIBERIX verkry nie.

**VOORDAT JY HIBERIX GEGEE WORD:**

**Jou kind behoort nie HIBERIX gegee te word nie indien:**

- hy/sy vantevore ’n allergiese reaksie teen HIBERIX, of enige bestanddeel wat hierdie vaksien bevat, gehad het. Die aktiewe stof en ander bestanddele in HIBERIX word aan die begin van hierdie brosjure gelys. Tekens van ’n allergiese reaksie mag ’n jeukerige vel, veluitslag, kortasem en swelling van die gesig of tong insluit.

Indien bogenoemde al met jou kind gebeur het, moet jy jou dokter of gesondheidsorgkundige daarvan vertel voordat die inspuiting gegee word.

**Spesiale sorg moet met HIBERIX geneem word:**

- as jou kind ’n ernstige infeksie met ’n hoë koors het. In sulke gevalle sal die vaksinering uitgestel word totdat herstel plaasvind. ’n Minder ernstige infeksie, soos ’n verkoue, behoort nie ’n probleem te wees nie, maar gesels eers met jou dokter daaroor

- as jou kind asemhalingsprobleme het, kontak asseblief jou dokter. Dit mag meer algemeen voorkom in die eerste drie dae na vaksinering indien jou kind prematuur gebore was (voor of op 28 weke van swangerskap).

Floutes kan na, of selfs voor, enige inspuiting met 'n naald voorkom, en dus moet jy die dokter of verpleegster vertel indien jou kind met 'n vorige inspuiting flou geword het.

**Neem van ander medisyne saam met HIBERIX**:

Indien jou kind ander medisyne gereeld neem, insluitend komplementêre of tradisionele medisyne, kan die gebruik van HIBERIX saam met hierdie medisyne ongewenste interaksies veroorsaak. Raadpleeg asseblief jou dokter vir advies.

In besonder moet jy jou dokter of apteker vertel as jou kind enige medisyne neem of 'n infeksie het wat die immuunsisteem (die liggaam se natuurlike verdedigingsisteem) affekteer, omdat jou kind nie die volle voordeel van HIBERIX mag verkry nie.

HIBERIX kan terselfdertyd as ander vaksienes van die kinderjare gegee word. 'n Verskillende inspuitingsplek sal vir elke vaksien gebruik word.

**HOE OM HIBERIX TE ONTVANG:**

HIBERIX word gewoonlik as drie aparte inspuitings op die ouderdom van 6-, 10- en 14-weke, gegee.

Indien addisionele inspuitings (versterkers) nodig is, sal die verpleegster of dokter jou daarvan vertel.

HIBERIX word gewoonlik in 'n spier ingespuit; by pasiënte met 'n bloedversteuring, mag dit egter onder die vel ingespuit word.

Die vaksien moet NIE in 'n vene ingespuit word NIE.

**Indien jou kind 'n dosis HIBERIX nie ontvang nie:**

Indien jou kind ’n geskeduleerde dosis nie ontvang nie, is dit belangrik dat jy so gou as moontlik ’n ander afspraak maak. Indien jy nie die hele vaksineringskursus van drie inspuitings klaarmaak nie, mag jou kind nie die beste reaksie op, en beskerming van die vaksien verkry nie.

**MOONTLIKE NEWE-EFFEKTE:**

HIBERIX kan newe-effekte veroorsaak.

Nie alle newe-effekte wat vir HIBERIX aangemeld is, word in hierdie brosjure ingesluit nie. Indien jou algemene gesondheid sou vererger of as jy enige negatiewe effekte ervaar terwyl HIBERIX geneem word, moet jy asseblief jou dokter, apteker of ander gesondheidsorgkundige vir advies raadpleeg.

**Allergiese reaksies:**

Soos met alle inspuitbare vaksiene, mag jou kind ’n allergiese reaksie ondervind.

Allergiese reaksies kom baie selde voor.

Die tekens van ’n allergiese reaksie mag insluit:

- veluitslae wat mag jeuk of blase vorm
- swelling van die oë en gesig
- probleme met asemhaling of sluk.

Hierdie reaksies begin gewoonlik kort nadat die inspuiting toegedien is. Indien dit sou gebeur nadat julle die kliniek verlaat het, moet jy jou kind dadelik na ’n dokter neem.

Vertel jou dokter onmiddellik of gaan na die noodafdeling van jou naaste hospitaal as jy van enigeen van die volgende ernstige newe-effekte bewus word.

- ineenstorting, verlies van bewussyn, gebrek aan bewustheid
- stuipe.

**Ander newe-effekte sluit in**:

- pyn, rooiheid en swelling by die inspuitingsplek
- hoë koors, verlies aan aptyt
- gevoel van rusteloosheid
- braking (siek word), diarree
- ongewone huil.

**Die volgende newe-effekte mag ook voorkom:**

- floute as gevolg van inspuiting
- gevoel van slaperigheid
- tydelik ophou asemhaal
- galbulte, veluitslag
- groot swelling van die ingespuite ledemaat
- harde bult by die inspuitingsplek.

Indien enige van hierdie newe-effekte ernstig word, vertel asseblief jou dokter of apteker daarvan.

Indien jy bewus word van enige newe-effekte wat nie in hierdie brosjure genoem word nie, moet jy asseblief jou dokter of apteker daarvan vertel.

**BERGING EN WEGDOENING VAN HIBERIX:**

Bewaar alle medisyne buite die bereik en sig van kinders.

Bewaar by +2 °C tot +8 °C (in 'n yskas).

MOENIE VRIES NIE. Raak van die vaksien ontslae as dit gevries het.

Bewaar in die oorspronklike verpakking om dit teen lig te beskerm.

Moenie na die vervaldatum wat op die etiket en verpakking aangedui word, gebruik nie. Die vervaldatum verwys na die laaste dag van daardie maand.

Raak van enige ongebruikte hersaamgestelde oplossing ontslae.

Medisyne behoort nie in rioolwater of huishoudelike afval weggegooi te word nie. Vra jou apteker hoe om van medisyne ontslae te raak wat nie langer benodig word nie. Hierdie maatreëls sal help om die omgewing te beskerm.

**AANBIEDING VAN HIBERIX:**

Die vaksien word aangebied in 'n 3 ml helder glasflessie wat met 'n rubberprop verseël word.

Die verdunningsmiddel (vloeistof) word in 'n 3 ml helder glasflessie of 'n voorafgevulde spuit, aangebied.

**IDENTIFIKASIE VAN HIBERIX:**

Die vaksien is 'n wit koekie of poeier, wat na vermenging met die verdunningsmiddel 'n helder, kleurlose vloeistof vry van sigbare partikels is.

Die verdunningsmiddel is 'n helder, kleurlose, reuklose vloeistof, vry van sigbare partikels.

Die hersaamgestelde oplossing is 'n helder, kleurlose vloeistof, vry van sigbare partikels.

**REGISTRASIENOMMER:**

32/30.1/0349

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