22/12/2020

אקט-היב /-ACT-HIB LYOPHILIZED POWDER FOR INJECTION

(HAEMOPHILUS B 10 MCG / 0.5 ML)

רופא/ה נכבד/ה ,רוקח/ת נכבד/ה,

חברת מדיצ'י מדיקל בע"מ מודיעה על עדכון העלון לרופא. בהודעה זו מצוינים סעיפים בהם נעשה שינוי מהותי או שינוי המהווה החמרה. עדכונים נוספים אשר אינם מהווים החמרה או שאינם מהותיים, אינם נכללים בהודעה זו (החמרה מסומנת ברקע צהוב).

ההתוויה הרשומה לתכשיר בישראל:

Prevention in infants of invasive diseases caused by Haemophilus influenzae type B (meningitis septicemia cellulitis arthritis epiglotitis).

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:.

[…]

WARNINGS AND PRECAUTIONS

[…]

Guillain-Barré Syndrome

If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give any tetanus toxoid-containing vaccine, including ActHIB vaccine, should be based on careful consideration of the potential benefits and possible risks.

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Interference with Laboratory Tests

Urine antigen detection may not have a diagnostic value in suspected disease due to *H. influenzae* type b within 1 to 2 weeks after receipt of a *H. influenzae* type b-containing vaccine, including ActHIB *[see Drug Interactions (7.3)]*.

ADVERSE REACTIONS

Clinical Trials Experience

[…]

In a US trial, the safety of ActHIB vaccine was evaluated in 110 children 15 to 20 months of age. All children received three doses of *Haemophilus influenzae* type b conjugate vaccine (ActHIB vaccine or a previously licensed Haemophilus b conjugate vaccine) at approximately 2, 4, and 6 months of age. The incidence of selected solicited injection site and systemic adverse reactions which occurred within 48 hours following the dose of ActHIB vaccine is shown in **Table 1**.

Table 1: Local and Systemic Reactions at 6, 24, and 48 Hours Following Immunization

with ActHIB Vaccine in Children 15 to 20 months old

Adverse Event	6 Hrs. Post-dose	24 Hrs. Post-dose	48 Hrs. Post-dose
Local (%)	**N=110**	**N=110**	**N=110**
Tenderness	20.0	8.2	0.9
Erythema (>1")	0.0	0.9	0.0
Induration*	5.5	3.6	0.9
Swelling	3.6	1.8	0.0
Systemic (%)	**N=103-110**	**N=105-110**	**N=104-110**
Fever (>102.2°F) (>39.0°C)	0	1.0	1.9
Irritability	27.3	20.9	12.7
Drowsiness	36.4	17.3	12.7
Anorexia	12.7	10.0	6.4
Vomiting	0.9	0.9	0.9
Persistent cry	0	0	0
Unusual cry	0	0	0

* Induration is defined as hardness with or without swelling.

In a US clinical trial (P3T06), 1,454 children were enrolled and received one dose of ActHIB vaccine at 2 months of age and subsequent doses administered at 4 and 6 months of age (concomitantly with DAPTACEL [a US-licensed diphtheria, tetanus and pertussis vaccine], IPOL [a US-licensed inactivated poliovirus vaccine] and PCV7 [Pneumococcal conjugate vaccine, 7-valent]) vaccines at 2, 4, and 6 months of age and hepatitis B vaccine at 2 and 6 months of age). At 15-16 months of age, 418 children received a 4th dose of ActHIB and DAPTACEL vaccines. The most frequent systemic reactions following any dose (>50% of participants) were decreased activity/lethargy, fussiness/irritability, and inconsolable crying.

Table 2: Number (Percentage) of Children with Selected Solicited Systemic Adverse Reactions by Severity Occurring within 0-3 days After Vaccination in Study P3T06

Systemic Reactions	DAPTACEL + IPOL + ActHIB Vaccines			DAPTACEL + ActHIB Vaccines
	Dose 1 N=1,390-1,406 %	Dose 2 N=1,346-1,360 %	Dose 3 N=1,301-1,312 %	Dose 4 N=379-381 %
Fever*†				
≥38.0°C	9.3	16.1	15.8	8.7
>38.5°C	1.6	4.3	5.1	3.2
>39.5°C	0.1	0.4	0.3	0.8
Decreased Activity/Lethargy‡				
Any	51.1	37.4	33.2	24.1
Moderate or Severe	24.3	15.8	12.7	9.2
Severe	1.2	1.4	0.6	0.3
Inconsolable Crying				
Any	58.5	51.4	47.9	36.2
≥1 hour	16.4	16.0	12.2	10.5
>3 hours	2.2	3.4	1.4	1.8

Fussiness/Irritability				
Any	75.8	70.7	67.1	53.8
≥1 hour	33.3	30.5	26.2	19.4
>3 hours	5.6	5.5	4.3	4.5

Note. - Ages of study participants ranged from 1.3 to 19.5 months.

* Fever is based upon actual temperatures recorded with no adjustments to the measurement route.

† Following Doses 1- 3 combined, the proportion of temperature measurements that were taken by axillary, rectal or other routes, or not recorded were 4 4 .8%, 54 .0%, 1.0%, and 0.1%, respectively. Following Dose 4 , the proportion of temperature measurements that were taken by axillary, rectal or other routes, or not recorded were 61.1%, 36.6%, 1.7%, and 0.5%, respectively.

‡ Moderate: interferes with or limits usual daily activity; Severe: disabling, not interested in usual daily activity.

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Post marketing Experience

The following events have been spontaneously reported during the post-approval use of ActHIB vaccine. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

- **Immune system disorders:**
  Anaphylaxis, other allergic/hypersensitivity reactions (including urticaria, angioedema)
- **Nervous system disorders:**
  Convulsions
- **General disorders and administration s ite conditions:**
  Extensive limb swelling, peripheral edema, pruritus, rash (including generalized rash)

[…]

8.4 Pediatric Use

Safety and effectiveness of ActHIB have not been established in infants below the age of 6 weeks and children and adolescents 6 years of age and older [see Dosage and Administration (2.1)].

[…]

קיימים עדכונים נוספים . למידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות:

https://data.health.gov.il/drugs/index.html#!/byDrug

וניתן לקבלו מודפס על ידי פניה לבעל הרישום מדיצ'י מדיקל בע"מ, רחוב המחשב 3 נתניה טלפון 7446170-09

בברכה,

האלה ביאדסה,

רוקחת ממונה