29 July 2021

AVAXIM 80 U PEDIATRIC / suspension for injection\ 80 אווקסים פדיאטרי

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 (שינוי שהינו הוספה או שינוי ניסוח מסומן כך, מחיקה מסומנת- ~~כך~~ והחמרה מסומנת ברקע צהוב).

ההתוויה הרשומה לתכשיר בישראל:

Avaxim 80 u pediatric is indicated for active immunisation against infection caused by Hepatitis a virus in children aged from 12 months to 15 years inclusive, who are at risk either of contaminating or spreading infection or of a life threatening disease if infected.

עדכונים מהותיים נעשו בסעיפים הבאים בעלון לרופא:

[…]

been studied.

4.8 Undesirable effects

a. Summary of the safety profile

More than 6200 children aged from 12 months to 15 years ~~(around 7000 administered doses)~~ were vaccinated with AVAXIM 80 U PEDIATRIC during clinical trials.

Most undesirable effects were moderate and limited to the first few days following vaccination with spontaneous recovery. Reactions were more rarely reported after the booster dose than after the first dose.

However, as with all pharmaceuticals, expanded commercial use of the vaccine might reveal rarer undesirable effects.

b. Tabulated list of adverse reactions

The undesirable effects are derived from clinical studies and worldwide post-marketing experience.

In each System Organ Class, the undesirable effects are ranked under headings of frequency, the most common reactions coming first, using the following convention:

Very common (≥1/10)

Common (≥1/100, <1/10)

Uncommon (≥1/1 000, <1/100)

Rare (≥1/10 000, <1/1000)

Very rare (<1/10 000)

Not known: cannot be estimated from the available data.

The table below summarize the frequencies of the adverse reactions that were recorded after the first dose, after the booster dose or after any dose of AVAXIM 80 U PEDIATRIC.

Adverse reactions	Frequency after the primary dose	Frequency after the booster dose	Frequency after any dose
Immune system disorders			
Anaphylactic reaction	Not known	Not known	Not known
Metabolism and nutrition disorders			

Adverse reactions	Frequency after the primary dose	Frequency after the booster dose	Frequency after any dose
Appetite decrease	Common	Common	Common
Psychiatric disorders			
Abnormal crying	Very common	Uncommon	Very common
Irritability	Common	Common	Common
Insomnia	Common	Common	Common
Nervous system disorders			
Cephalalgia	Common	Common	Very common
Vasovagal syncope in response to injection	Not known	Not known	Not known
Seizures with or without fever	Not known	Not known	Not known
Gastrointestinal disorders			
Abdominal pain	Common	Common	Common
Diarrhoea	Common	Common	Common
Nausea	Common	Common	Common
Vomiting	Common	Common	Common
Skin and subcutaneous tissue disorders			
Rash	NR*	Uncommon	Uncommon
Urticaria	Uncommon	NR*	Uncommon
Musculoskeletal and connective tissue disorders			
Arthralgia	Common	Uncommon	Common
Myalgia	Common	Common	Common
General disorders and administration site conditions			
Local reactions			
Pain at the injection site	Very common	Common	Very common
Redness at the injection site	Common	Common	Common
Induration or oedema at the injection site	Common	Common	Common
Haematoma at the injection site	Common	Uncommon	Common
Systemic reactions			
Malaise	Common	Common	Very common
Fever	Common	Common	Common
Asthenia or somnolence	Common	Common	Common

* Not reported during clinical studies

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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 - 097446170

ירון חסיד,

רוקח ממונה - מדיצ'י מדיקל בע"מ