



15/7/2020

\ AVAXIM 80 U PEDIATRIC (Hepatitis a vaccines/ 80 units / 0.5 ml suspension for injection

אוקסים פדיאטרי U 80

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

חברת מדיצי' 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 **בכחול**, מחיקה מסומנת **באדום** 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:

[...]

**4.4 Special warnings and ~~special~~ precautions for use**

[...]

Syncope (fainting) can occur following ~~injection~~, or even before, any vaccination as a psychogenic response to the needle injection, especially in adolescents. This may be accompanied by several neurological signs such as transient sight disorders, paraesthesia and tonic-clonic limb movements during the recovery phase. It is important that procedures be in place to avoid any injury from faints.

[...]

As with ~~impaired immunity has been performed~~ all vaccines, **vaccination may not induce a protective response in some vaccinees.**

[...]

**4.8 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 ( $\geq 1/10$ )

Common ( $\geq 1/100, < 1/10$ )

Uncommon ( $\geq 1/1\ 000, < 1/100$ )

Rare ( $\geq 1/10\ 000, < 1/1000$ )

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
<b>Metabolism and nutrition disorders</b>			
Appetite decrease	Common	Common	Common
<b>Psychiatric disorders</b>			
Abnormal crying	Very common	Uncommon	Very common
Irritability	Common	Common	Common
Insomnia	Common	Common	Common
<b>Nervous system disorders</b>			
Cephalalgia	Common	Common	Very common
Vasovagal syncope in response to injection	Not known	Not known	Not known
<b>Gastrointestinal disorders</b>			
Abdominal pain	Common	Common	Common
Diarrhoea	Common	Common	Common
Nausea	Common	Common	Common
Vomiting	Common	Common	Common
<b>Skin and subcutaneous tissue disorders</b>			
Rash	NR*	Uncommon	Uncommon
Urticaria	Uncommon	NR*	Uncommon
<b>Musculoskeletal and connective tissue disorders</b>			
Arthralgia	Common	Uncommon	Common
Myalgia	Common	Common	Common
<b>General disorders and administration site conditions</b>			
<i>Local reactions</i>			
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
<i>Systemic reactions</i>			
Malaise	Common	Common	Very common
Fever	Common	Common	Common
Asthenia or somnolence	Common	Common	Common

\* Not reported during clinical studies

\* [...]

## 6.6 Instructions Special precautions for use disposal and other handling

Shake before injection ~~to obtain~~, until a homogenous suspension is obtained.

The vaccine must be visually inspected before administration to verify the absence of foreign particles.

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

[...]

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 מדיצי' מדיקל בע"מ, רחוב המחשב 3 נתניה טלפון 09-7446170

בברכה,

האלה ביאדסה,

רוקחת ממונה