

**הנדון : Imovax dT \ אימווקס dT
Suspension for injection**

חברת מדיצי' מדיקל בע"מ מבקשת להודיע על עדכון העלון לרופא של החיסון Imovax dT \ אימווקס dT.

עדכוני העלון מפורטים מטה

Indication: This vaccine is indicated for adults over 18 years of age in the following cases:

- routine booster vaccinations against diphtheria and tetanus. The diphtheria toxoid content is reduced to one

tenth of the normal dose to minimize the risks of a severe hypersensitivity reaction.

- primary vaccination.

- post-exposure prophylaxis following a tetanus-prone wound, if a booster diphtheria injection is required.

This adsorbed diphtheria and tetanus vaccine may be administered as a booster vaccination in children over 10 years of age in whom poliomyelitis is prevented by separate administration of poliomyelitis vaccine.

מקרא לסימון העדכונים: טקסט חדש – **נראה כר**, מחיקה – **נראה כר**.

[...]

Special warnings and precautions for use

As with all injectable vaccines, appropriate medical treatment should always be readily available and supervision provided in case of an anaphylactic reaction following administration of the vaccine.

An immunosuppressive treatment or an immunodeficiency condition may induce a decrease in the immune response to the vaccine. It is therefore recommended to wait for the end of the treatment for the vaccination or to make sure that the subject is well protected. However, the vaccination of subjects with chronic immunodepression, such as HIV infection, is recommended if the underlying disease allows an antibody response, even if limited.

In order to prevent hypersensitivity reactions, avoid administering the vaccine to persons who have received a complete primary vaccination or a booster dose in the previous 5 years.

If Guillain-Barré syndrome or brachial neuritis has occurred following receipt of prior vaccine containing tetanus toxoid, the decision to give any vaccine containing tetanus toxoid should be based on careful consideration of the potential benefits and possible risks. Vaccination is usually justified when primary immunisation schedules are incomplete (i.e., fewer than three doses have been received).

Do not inject by the intravascular route. Make sure the needle does not penetrate a blood vessel.

Syncope (fainting), a psychogenic reaction to an injection with a needle, may occur after, or even before, any vaccination. Measures must be implemented to prevent any injuries due to fainting, and to manage syncopal reactions.

Imovax dT contains less than 1 mmol (39 mg) potassium and less than 1 mmol (23 mg) sodium per dose, that is to say essentially "potassium-free" and "sodium-free".

Traceability:

In order to improve traceability of biological medicinal products, the name and batch number of the administered medicinal product must be clearly recorded.

[...]

יש 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#!/medDetails/160%2019%2035153%2000> וניתן לקבלו מודפס על ידי פניה

לחברת מדיצי' מדיקל בע"מ, רח' המחשב 3 נתניה, בטלפון 09-7446170.