הודעה על החמרה (מידע בטיחות)

תאריך _____29.08.2011_____

שם תכשיר באנגלית_____ Imovax dT

מספר רישום_____14462 3323200_____

שם בעל הרישום___מדיצ'י מדיקל בע"מ

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השינויים בעלון מסומנים ברקע צהוב

עלון לרופא

פרטים על השינוי/ים המבוקש/ים		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
Contraindications	- Hypersensitivity to one of the ingredients of the vaccine. - Hypersensitivity reaction or neurological disorder after a previous injection of vaccine.	- Hypersensitivity to one of the ingredients of the vaccine. Vaccination should be postponed in the event of fever, acute disease in particular with an infection cause or chronic progressive illness unless it is absolutely indicated e.g. lethal risk associated with tetanus-prone wound. - Hypersensitivity reaction or neurological disorder after a previous injection of vaccine.
Special precautions	Do not inject by the intravascular route. Ensure that the needle does not enter a blood vessel. ~~Vaccination should be postponed in the event of fever, acute disease in particular with an infection cause or chronic progressive illness unless it is absolutely indicated e.g. lethal risk associated with tetanus-prone wound.~~ 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 an infection with HIV, is recommended if the subjacent 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.	Do not inject by the intravascular route. Ensure that the needle does not enter a blood vessel. As with every injectable vaccine, a suitable medical treatment should be available to deal with a potential anaphylactic shock immediately after administration. 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 an infection with HIV, is recommended if the subjacent 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-Barre 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 immunization schedules are incomplete (i.e. fewer than three doses have been received).

Based on spontaneous reporting the following adverse events have been reported during the commercial use of Imovax dT. These events have been rarely (<0.01%) reported, however exact incidence rates cannot precisely be calculated. **Blood and lymphatic system disorders**: Lymphadenopathy **Immune system disorders**: Type I hypersensitivity reactions **Nervous system disorders**: cephalagia, malaise **Vascular disorders**: hypotension (with context of Type I hypersensitivity reactions **Skin and subcutaneous tissue** disorders: allergic like symptoms such as generalized pruritus, urticaria or oedema **Musculoskeletal and connective tissue disorders**: myalgia, arthralgia **General disorders and administration site condition**: Injection site reactions such as pain, rash, induration or oedema, which can occur within 48 hours and persist for one or two days. The formation of a sub-cutaneous nodule can sometimes accompany these reactions. Cases of aseptic abscesses have exceptionally been reported. Trancient pyrexia. Malaise. All these reactions have been observed more frequently in hyper immunized subjects, particularly in case of over-frequent boosters. Potential adverse events (i/.e. adverse events which have not been reported directly with Imovax dT, but with other vaccines containing one or more of the constituents of Imovax dT): Brachial neuritis and Gullian-Barre Syndrome after administration of a tetanus toxoid containing vaccine.	~~Local reactions at the injection site: pain, erythema, induration and oedema may occur within 48 hours and persist for one or two days. These reactions may be associated with a sub-cutaneous nodule. Rare aseptic abscesses have been reported.~~ ~~Systemic reactions: transient fever associated or not associated with a local reaction and lymphadenopathy, immediate hypersensitivity reactions such as pruritus, generalized urticaria or oedema, dizziness, hypotension, myalgia, arthralgia and headaches may occur.~~ ~~These reactions are more likely to be observed in hyperimmunized subjects, particularly after over-frequent booster injections.~~ ~~Neurological disorders resulting from a vaccination against diphtheria and/or tetanus are extremely rare and no causal relationship has been clearly demonstrated.~~	**Adverse events**