הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך ____06.05.12____

שם תכשיר באנגלית____Imovax dt

מספר רישום___ 144 62 33232 00_____

שם בעל הרישום:__ _מדיצ'י מדיקל בע"מ _____

השינויים סומנו בצהוב

פרטים על השינוי/ים המבוקש/ים		
טקסט חדש	טקסט נוכחי	פרק בעלון
For routine booster injections, a single dose of 0.5 ml should be administrated every 10 years is recommended. For primary vaccination 3 successive 0.5 ml doses should be administrated at monthly intervals. Given the adsorbed nature of the vaccine, it is preferable to administer it by the intramuscular route in order to minimize local reactions. The recommended sites are the antero-lateral face of the thigh or arm See instructions for use paragraph 6.6.	For routine booster injections, a single dose of 0.5 ml every 10 years is recommended. The primary vaccination consists of 3 successive 0.5 ml doses at monthly intervals. Given the adsorbed nature of the vaccine, it is recommended to administer it by the intramuscular route in order to minimize local reactions. The recommended sites are the antero-lateral face of the thigh or arm See instructions for use § 6.6.	**4.2 Posology and method adninistration**
~~Do not inject by the intravascular route. Ensure that the needle does not enter a blood vessel.~~ As with every injectable vaccines appropriate medical treatment should always be readily available and supervision provided in case of an anaphylactic react ion following administration ***of*** *the vaccine*	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.	**4.4 Special warnings and precaution for use**
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 immunosuppressive, such as HIV infection, is recommended if the underlying disease allows an antibody response, even if limited. Do not inject by the intravascular route. Make sure the needle does not penetrate a blood vessel	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 immunosuppressive, such as an infection with HIV, is recommended if the subjacent disease allows an antibody response even if limited.	

There is no contraindication to the administration of this vaccine during a vaccination session with other common vaccines ~~has been reported~~.	No contraindication to the administration of this vaccine during a vaccination session with other common vaccines has been reported.	**4.5. Interaction with other medicinal and other forms of interaction**
As regards Diphtheria vaccine Clinically, no deformity or fetotoxic effects have been reported to date. However follow up of pregnant women exposed to the diphtheria vaccine is insufficient to rule out all risk. As regards Tetanus vaccine Considering the experimental and clinical data ,~~currently available~~ this vaccine may be prescribed at any stage of pregnancy if needed.	As regards Diphtheria vaccine Clinically, no deformity or fetotoxic effects have been reported to date. Data regarding cases of vaccination of pregnant women are currently insufficient to rule out all risk. As regards Tetanus vaccine Considering the experimental and clinical data currently available, this vaccine may be prescribed at any stage of pregnancy.	**4.6. Pregnancy and lactation**
Buffer solution containing sodium chloride, disodium dihydrate phosphate, monopotassium phosphate and water ~~for preparation~~ for injection	Buffer solution containing sodium chloride, disodium dihydrate phosphate, monopotassium phosphate and water for preparations for injection.	**6.1 List of excipients**
3 years After opening : the product should be used immediately	3 years	**6.3 Shelf life**
Store in a refrigerator (2°C - 8°C) Do not freeze.	Store at a temperature between + 2°C and + 8°C (in a refrigerator). Do not freeze	**6.4 Special precautions for storage**
.5 ml of suspension in a prefilled syringe (glass) ~~equipped~~ with a plunger stopper (bromobutyl or chlorobutyl or bromochlorobutyl) – box of 1 or 10.	.5 ml of suspension in a prefilled syringe (glass) equipped with a plunger stopper (bromobutyl or chlorobutyl or bromochlorobutyl) – box of 1 or 10.	**6.5 Nature and contents of container**
Shake before injection, until a homogenous suspension is obtained. Any unused product or waste material should be disposed of in accordance with local requirements	Shake before injection, until a homogenous suspension is obtained.	**6.6 Instructions for use and handling**