הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

אושר – 6.16

תאריך _____05.06.16_____

שם תכשיר באנגלית ומספר הרישום

_____VAXIGRIP _031 -05 -21760 -00

שם בעל הרישום_מדיצי מדיקל בע"מ_____

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
2. **Qualitive and Quantitive composition**	**שינוי הרכב 2016-2017**	• A/California/7/2009 (H1N1)pdm09– like virus ….15 micrograms HA** • A/Hong Kong/4801/2014 (H3N2) -like virus 15 micrograms HA** • B/Brisbane/60/2008 –like virus 15 micrograms HA**
4.1 **Terapeutic indications**	**תוספת טקסט**	VAXIGRIP is indicated in adults and children from 6 months of age.
4.2 **Posology and method of**	**תוספת ועדכון טקסט**	**Posology** Adults: 0.5 ml.

Paediatric population Children aged 36 months onwards: 0.5 ml. Children aged 6 to 35 months: 0.25 ml. Clinical data are limited. See Section 6.6 for more information on administration of the 0.25 ml dose. A 0.5 ml dose may be given, if this is required by national recommendations. For children aged less than 9 years who have not previously been vaccinated, a second dose should be given after an interval of at least 4 weeks. Children aged less than 6 months: the safety and efficacy of VAXIGRIP in children aged less than 6 months have not been established. No data are available. **Method of administration** To be administered via intramuscular or deep subcutaneous route. adults and children from 36 months of age: the preferred site for intramuscular injection is the deltoid muscle. r children from 12 to 35 months of age: the preferred site r intramuscular injection is the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate). For children from 6 to 11 months of age: the preferred site for intramuscular injection is the anterolateral aspect of the thigh. *Precautions to be taken before handling or administering the medicinal product.* For instructions for preparation of the medicinal product before administration, see Section 6.6.		**administration**
Hypersensitivity to the active substances, to any of the excipients listed in Section 6.1 or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde and octoxinol-9. Vaccination should be postponed in case of modera severe febrile disease or acute disease	**עדכון טקסט**	**4.3** **Contraindications**
As with other vaccines administered intramuscularly the vaccine should be administered with caution to subjects with thrombocytopenia or bleeding disorders since bleeding may occur following intramuscular administration to these subjects. As with any vaccine, vaccination with VAXIGRIP may not protect 100% of susceptible subjects Interference with serological testing	**תוספת טקסט**	**4.4**

4.8 **Undesirable effects**	**עדכון** **טקסט**	**בעלון המצורף**
4.9 **Overdose**	**עדכון** **טקסט**	Cases of administration of more than the recommended dose (overdose) have been reported with VAXIGRIP. When adverse reactions were reported, the information was consistent with the known safety profile of VAXIGRIP described in Section 4.8.

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.

שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

הועבר בדואר אלקטרוני בתאריך.....05/06/16.....