Attidim Science Park, Bldg 4,
P.O.B 58099
Tel Aviv 61580
Israel

T: +972-3-7691000
F: +972-3-6494973

Abbott

ספטמבר 2020

רופא/ה, רוקח/ת נכבד/ה,

אינפלובאק
INFLUVAC®

SEASON 2020/2021 עונה

Trivalent Influenza Vaccine
Suspension for Injection

אבוט מעבדות רפואית בע"מ מבקשת לעדכן על השינויים הבאים בעלון התכשיר:

עדכון זני השפעת לעונה 2020/2021:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus surface antigens (inactivated) (haemagglutinin and neuraminidase) of the following strains*:

- A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like strain (A/Guangdong-Maonan/SWL1536/2019, CNIC-1909)	15 micrograms HA **
- A/Hong Kong/2671/2019 (H3N2)-like strain (A/Hong Kong/2671/2019, IVR-208)	15 micrograms HA **
- B/Washington/02/2019 -like strain (B/Washington/02/2019, wild type)	15 micrograms HA **
	per 0.5 ml dose

* propagated in fertilised hens' eggs from healthy chicken flocks
** haemagglutinin.

This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and EU recommendation for the 2020/2021 season.

בנוסף העלון עודכן בעדכונים המהותיים הבאים:

4.4. Special warnings and precautions for use

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

Influvac should under no circumstances be administered intravascularly.

As with other vaccines administered intramuscularly, Influvac should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to these subjects.

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

Influvac is not effective against all possible strains of influenza virus. Influvac is intended to provide protection against those strains of virus from which the vaccine is prepared and to closely related strains.
As with any vaccine, a protective immune response may not be elicited in all vaccinees.
Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

Interference with serological testing: see section 4.5.

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium- free'.
This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially "potassium-free".

בהודעה זו מצויינים העדכונים העיקריים. לעדכונים נוספים ומידע נוסף יש לעיין בעלון לרופא המעודכן.

העלון נשלח למשרד הבריאות לצורך העלאתו למאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פניה לבעל הרישום, אבוט מעבדות רפואיות בע"מ, קריית עתידים, ת.ד 58099 ת"א או בטלפון 03-7691000

בברכה,

לירן מימון
רוקחת ממונה