ינואר 2024

Efluelda

חומר פעיל:

Influenza virus (inactivated, split) of the following strains*:

A/Victoria/4897/2022 (H1N1) pdm09-like strain (A/Victoria/4897/2022, IVR-238) - 60 micrograms HA**

A/Darwin/9/2021 (H3N2)-like strain (A/Darwin/9/2021, SAN-010) - 60 micrograms HA**

B/Austria/1359417/2021-like strain (B/Michigan/01/2021, wild type) - 60 micrograms HA**

B/Phuket/3073/2013-like strain (B/Phuket/3073/2013, wild type) - 60 micrograms HA**

Per 0.7 ml dose

*propagated in embryonated chicken eggs

**haemagglutinin

ההתוויה המאושרת:

Active immunisation in adults 65 years of age and older for the prevention of influenza disease.

חברת סאנופי מבקשת להודיע על עדכון העלון לצרכן במתכונת עלון לרופא.

העלון ובו מסומנים העדכונים העיקריים מצורף למכתב זה.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום - סאנופי ישראל בע"מ, Greenwork Park, מתחם העסקים בקיבוץ יקום, בניין E (קומה 1), 6097600, יקום או בטלפון: 09-8633081.

להלן הקישור לאתר משרד הבריאות: https://israeldrugs.health.gov.il/#!/byDrug

בברכה,

חברת סאנופי ישראל בע"מ

Greenwork Park, Yakum, Building E, 1st floor, 6097600, Israel
Tel.: +972-9-8633081 - Fax: +972-9-8851444 - www.sanofi.co.il

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Efluelda , suspension for injection in pre-filled syringe

Quadrivalent influenza vaccine (split virion, inactivated), 60 micrograms HA/strain

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus (inactivated, split) of the following strains*:

A/~~Michigan/45/2015~~Victoria/4897/2022 (H1N1) pdm09-like strain (A/Victoria/4897/2022, IVR-238)~~Michigan/45/2015, ... NYMC X-275 .....~~60 micrograms HA**

A/~~Singapore/INFIMH-16-0019/2016~~Darwin/9/2021 ~~—~~(H3N2)-like ~~–~~strain ~~—~~ (A/Darwin/9/2021, SAN-010~~Singapore/INFIMH-16- 0019/2016, IVR-186~~) 60 micrograms HA**

B/~~Colorado/6/2017-like strain (B/Maryland/15/2016, NYMC BX-69A)~~

~~-~~Austria/1359417/2021-like strain (B/Michigan/01/2021, wild type) 60 micrograms HA**

B/Phuket/3073/2013-like strain (B/Phuket/3073/2013, wild type) ..... 60 micrograms HA**

Per 0.7 ml dose

* propagated in embryonated chicken eggs

** haemagglutinin

This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU decision for the ~~2018~~2023/~~2019~~ 2024 season.

Efluelda may contain traces of eggs, such as ovalbumin, formaldehyde which are used during the manufacturing process (see Section 4.3).

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

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4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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4.2 Posology and method of administration

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4.3 Contraindications

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4.4 Special warnings and precautions for use

Traceability
In order to improve the traceability of biological medicinal products, the name ~~and the batch number~~ of the administered product should be clearly recorded. It is recommended to record the batch number as well.

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4.5 Interaction with other medicinal products and other forms of interaction

Co-administration of Quadrivalent Influenza Vaccine (Split Virion, Inactivated) High Dose with an investigational booster 100 mcg dose of COVID-19 mRNA vaccine (nucleoside modified/elastomeran) has been evaluated in a limited number of participants in a descriptive clinical study (see sections 4. And 5.1).~~No interaction studies have been performed, nor data to assess the concomitant administration of Efluelda with other vaccines.~~

If Efluelda needs to be given at the same time as another injectable vaccine(s), immunisation should be carried out on separate limbs.

It should be noted that the adverse reactions may be intensified by any co-administration.

The immunological response may be reduced if the patient is undergoing immunosuppressant treatment.

Following influenza vaccination, false positive results in serology tests using the ELISA method to detect antibodies against HIV1, Hepatitis C and especially HTLV1 have been reported. An appropriate Western Blot test should be used to confirm or disprove the results of the ELISA test. The transient false positive reactions could be due to a non-specific IgM response induced by influenza vaccine.

4.6 Fertility, pregnancy and lactation

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4.7 Effects on ability to drive and use machines

Efluelda has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

a. Summary of the safety profile

Adverse event information is based on data coming from one clinical trial with Efluelda and on the clinical and post-marketing experience of Trivalent Influenza Vaccine (Split Virion, Inactivated) High-Dose (TIV-HD).

The safety of Efluelda was assessed in one randomized, active-controlled, modified double-blind Phase III clinical trial conducted in the US in which 2670 adults over 65 years of age received one dose (0.7 mL) ofEfluelda or TIV-HD. The safety analysis set included 1777 Efluelda recipients, 443 TIV-HD recipients, and 450 TIV-HD containing the alternate B influenza strain recipients.

The most common frequently reported adverse reactions occurring after Efluelda administration werevaccination was injection site pain (reported by 41.3%), % of study participants followed by myalgia (22.7%), headache (14.4%) and malaise (13.2%). The majorityMost of these reactions occurred and resolved within three days of vaccination.

Reactogenicity of the vaccine containing 60 micrograms haemagglutinin of each virus strain per dose iswas slightly increased as compared to the standard dose vaccine, but no major difference in intensity was observed.

The safety of Efluelda was evaluated in a descriptive study (QHD00028) in which subjects received Efluelda together with an investigational booster 100 mcg dose of COVID- 19 mRNA vaccine (nucleoside modified) (n=100), Efluelda only (n=92) or an investigational booster 100 mcg dose of COVID-19 mRNA vaccine (nucleoside modified) only (n=104). The frequency and severity of local and systemic adverse reactions was similar in subjects who were co-administered with Efluelda and licensed COVID-19 mRNA vaccine and subjects administered with a booster dose of licensed COVID-19 mRNA vaccine.

b. Tabulated list of adverse reactions

The data below summarizes the frequencies of adverse reactions that were recorded following vaccination with Efluelda during QHD00013 clinical trial (1777 adults 65 years of age and older) and adverse reactions reported during clinical development and post-marketing experience with TIV-HD (marked with * in the table below).

Adverse events are ranked under headings of frequency using the following convention:

Very common (≥1/10);

Common (≥1/100 to <1/10);

Uncommon (≥1/1,000 to <1/100);

Rare (≥1/10,000 to <1/1,000);

Very rare (<1/10,000);

Not known (cannot be estimated from available data).

ADVERSE REACTIONS	FREQUENCY
General Disorders and Administration Site Conditions	
Injection site pain, malaise	Very common
Injection site erythema, injection site swelling, injection site induration, injection site bruising, Shivering	Common
Fever (≥37.5°C), injection site pruritis. asthenia	Uncommon
Fatigue	Rare
Chest pain	Not known*
Musculoskeletal and Connective Tissue Disorders	
Myalgia	Very common
Muscle weakness	Uncommon
Arthralgia, ~~Pain~~ pain in extremities	Rare
Nervous System Disorders	
Headache	Very common
Lethargy	Uncommon
Dizziness	Rare
Guillain-Barré syndrome (GBS), convulsions, febrile convulsions, myelitis (including encephalomyelitis and transverse myelitis), facial palsy (Bell's palsy), optic neuritis/neuropathy, brachial neuritis, syncope (shortly after vaccination), paraesthesia	Not known*
Blood and Lymphatic System Disorders	

Thrombocytopenia, lymphadenopathy	Not known*

ADVERSE REACTIONS	FREQUENCY
Respiratory, Thoracic and Mediastinal Disorders	
Cough	Uncommon
Dyspnea, wheezing, throat tightness, oropharyngeal pain, and rhinorrhea	Not known*
Gastrointestinal Disorders	
Diarrhoea, nausea, dyspepsia	Uncommon
Vomiting	Rare
Immune System Disorders	
Night sweats, rash	Uncommon
Pruritus, urticaria	Rare
Anaphylaxis, other allergic/hypersensitivity reactions (including angioedema)	Not known*
Vascular Disorders	
Flushing	Rare
Vasculitis, vasodilatation	Not known*
Ear and Labyrinth Disorders	
Vertigo	Uncommon
Eye Disorders	
Ocular hyperemia	Not known*

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health (www.health.gov.il) according to the National Regulation by using an online form https://sideeffects.health.gov.il.

4.9 Overdose

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5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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Effectiveness Studies

Randomized Clinical Trials

A cluster-randomized, controlled clinical trial in United States nursing homes assessed the relative effect of TIV-HD versus a standard dose of influenza vaccine in hospitalizations among 53008 individuals during the 2013-2014 influenza season.

During the 2013-2014 season, the incidence of respiratory-related hospital admissions (primary objective) was significantly reduced in facilities where residents received TIV-HD

compared with those that received standard-dose influenza vaccines by 12.7% (adjusted risk ratio [ARR] 0.873, 95% CI 0.776 to 0.982, p=0.023). Moreover, with respect to secondary endpoints, TIV-HD reduced hospital admissions for pneumonia by 20.9% (ARR 0.791, 95% CI: 0.267 to 0.953, p=0.013) and all-cause hospital admissions by 8% (ARR 0.915, 95% CI: 0.863 to 0.970, p=0.0028).

Observational Studies

Several retrospective studies, over 8 influenza seasons and in more than 24 million individuals 65 years of age and older, confirmed the superior protection offered by TIV-HD compared to standard-dose influenza vaccines against complications of influenza such as pneumonia and influenza hospitalization (13.4% (95%CI: 7.3% to 19.2%, p<0.001)), cardio--

respiratory hospitalizations 17.9% (95%CI :14.9% to 20.9%, p<0.001) and all –cause hospitalization 8.1% (95%CI: 5.9% to 10.3%, p<0.001) ; although the impact may vary per season.

Concomitant Administration with COVID-19 mRNA Vaccine (nucleoside modified)

In a descriptive open-label clinical study (NCT04969276), healthy adults aged 65 years and older were divided in three groups: Group 1 received Efluelda alone (N=92), Group 2 (N=100) received Efluelda concomitantly with an investigational booster 100 mcg dose of COVID-19 mRNA vaccine (nucleoside modified) at least 5 months after the second dose of the primary series, Group 3 (N=104) received only the investigational booster 100 mcg dose of COVID-19 mRNA vaccine (nucleoside modified).

Co-administration resulted in no change to influenza vaccine immune responses as measured by hemagglutination inhibition (HAI) assay. Co-administration resulted in similar responses to COVID-19 mRNA vaccine, as assessed by an anti-spike IgG assay (see section 4.5 and 4.8).

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

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6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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6.2 Incompatibilities

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6.3 Shelf life

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6.4 Special precautions for storage

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6.5 Nature and contents of container

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6.6 Special precautions for disposal and other handling

The vaccine should be allowed to reach room temperature before use.

Shake before use.

The vaccines should be inspected visually for particulate matter and/or discoloration prior to administration whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.

The syringe is intended for single use only and should not be reused. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Sanofi Israel Ltd., Greenwork Park, P.O box 47, Yakum
~~Medici Medical Ltd, 3 Hamachshev St. Netanya 4250713, Israel~~

~~8 MANUFACTURER~~

~~Sanofi Pasteur France, 14 Espace Henry Vallee, 69007, Lyon, France~~

~~9~~8 MARKETING AUTHORISATION NUMBER(S)

169-15-36617

Revised in December 2023 according to MoH guidelines.

~~*This leaflet format has been determined by the Ministry of Health and the content has been checked and approved in Feb 2022*~~