ינואר 2024

# Imovax dT

חומר פעיל:

| | |
|---|---|
| Diphtheria Toxoid | 2 IU / 0.5 ML |
| Tetanus Toxoid | 20 IU / 0.5 ML |
| Aluminum Hydroxide | 0.6 MG / 0.6 ML |

ההתוויה המאושרת:

This vaccine is indicated for adults over 18 years of age in the following cases:

- Routine booster vaccinations against diphtheria and tetanus. The diphtheria toxoid content is reduced to one tenth of the normal dose to minimise the risks of a severe hypersensitivity reaction.
- Primary vaccination.
- Post-exposure prophylaxis following a tetanus-prone wound, if a booster diphtheria injection is required.

This adsorbed diphtheria and tetanus vaccine may be administered as a booster vaccination in children over 10 years of age in whom poliomyelitis is prevented by separate administration of poliomyelitis vaccine.

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

העלון ובו מסומנים העדכונים 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

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

**Imovax dT, suspension for injection in prefilled syringe**

**Adsorbed diphtheria and tetanus vaccine**

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Diphtheria toxoid .....≥ 2 I.U.

Tetanus toxoid .....≥ 20 I.U.

Adsorbed on hydrated aluminium hydroxide .....0.6 mg $Al^{3+}$

For one dose of 0.5 ml dose.

For a the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Suspension for injection in a prefilled syringe

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

This vaccine is indicated for adults over 18 years of age in the following cases:

- Routine booster vaccinations against diphtheria and tetanus. The diphtheria toxoid content is reduced to one tenth of the normal dose to minimise the risks of a severe hypersensitivity reaction.
- Primary vaccination.
- Post-exposure prophylaxis following a tetanus-prone wound, if a booster diphtheria injection is required.

This adsorbed diphtheria and tetanus vaccine (Imovax dT) may be administered as a booster vaccination in children over 10 years of age in whom poliomyelitis is prevented by separate administration of poliomyelitis vaccine.

### 4.2 Posology and method of administration

**PosologyDosage**

- For routine booster injections, a single dose of 0.5 mL ml should be givenadministered every 10 years.
- For primary vaccination, 3 successive doses of 0.5 mL mldoses should be administered 1 month apart.at monthly intervals.
- For prophylaxis in people exposed to a risk of tetanus, the following recommended schedule should be followed:
- The post-tetanus exposure prophylaxis recommendations are summarized below:

| TYPE OF WOUNDINJURY | PATIENT NOT IMMUNISED OR VACCINATION INCOMPLETEPARTIALLY IMMUNISED | PATIENT COMPLETELY FULLY IMMUNISED Time since last booster dose | |
|---|---|---|---|
| | | 5 to 10 years | >10 years |
| **Minor – clean** | **Begin Start or complete vaccination: Tetanus toxoid, 1 dose of 0.5 ml** | **No injectionNone** | **Tetanus toxoid: 1 dose of 0.5 ml** |
| **Major - clean or tetanus-prone** | In one arm: Human tetanus immunoglobulin, 250 IU* In the other arm: Tetanus toxoid**: 1 dose of 0.5 ml | Tetanus toxoid: 1 dose of 0.5 ml | **In one arm: Human tetanus immunoglobulin, 250 IU*** In the other arm: Tetanus toxoid: 1 dose of 0.5 ml* |

| | | | |
|---|---|---|---|
| **Tetanus-prone Delayed or incomplete debridement** | **In one arm: Human tetanus immunoglobulin, 500 IU*** In the other arm: Tetanus toxoid**: 1 dose of 0.5 ml Antibiotic therapy | Tetanus toxoid: 1 dose of 0.5 ml Antibiotic therapy | **In one arm: Human tetanus immunoglobulin, 500 IU*** In the other arm: Tetanus toxoid: 1 dose of 0.5 ml* Antibiotic therapy |

*Use different syringes, needles and injection sites.
**~~Complete~~ Update the vaccination status according to the vaccination schedule.

*Paediatric population*

Not applicable.

**Method of administration**

Precautions to be taken before handling or administering the medicinal product

Given the adsorbed nature of the vaccine, it is preferable to administer it intramuscularly~~by the intramuscular route~~ (IM) in order to ~~minimize~~ minimise local reactions. The recommended sites are: the anterolateral aspect~~antero-lateral faces~~ of the thigh or arm.

Deep subcutaneous~~The deep sub-cutaneous~~ (SC) ~~route~~ injection may also be used.

However, ~~the~~ intradermal ~~route must~~injection should not be used.

See "Special precautions for disposal and other handling", ~~-~~[section] 6.6.

## ~~4.9~~4.3 Contraindications

- Hypersensitivity to the active substance~~s~~ or to any of the excipients listed in section 6.1~~,~~ and to formaldehyde (which may be present in trace amounts due~~as traces owing~~ to its use during ~~the~~ manufacturing ~~process~~).
- In cases of fever, acute, particularly infectious, illness or chronic illness during an active phase, it is~~It is~~ preferable to postpone vaccination ~~in the event of fever, acute disease in particular with an infection cause or chronic progressive illness~~ unless ~~it is absolutely indicated e.g. if~~ there is an absolute indication, such as ~~a~~ lethal risk associated with tetanus in the event of a tetanus-prone wound.
- Hypersensitivity reaction or neurological disorder which occurred after a previous injection of a vaccine.

## ~~4.10~~4.4 Special warnings and precautions for use

As with ~~all~~ any injectable vaccine~~s~~, appropriate medical treatment should ~~always~~ be readily available and the patient should be closely monitored if ~~supervision provided in case of~~ an anaphylactic reaction occurs after the ~~following~~ administration of the vaccine.

Immunosuppressive~~An immunosuppressive~~ treatment or an immunodeficiency condition may induce a decrease in the immune response to the vaccine. It is therefore recommended to wait until~~for~~ the end of ~~the~~ treatment before vaccinating~~for the vaccination~~ or to ensure~~make sure~~ that the subject is well protected. Nevertheless~~However~~, the vaccination of chronically immunosuppressed subjects ~~with chronic immunodepression~~, such those infected with ~~as~~ HIV ~~infection~~, is recommended if the underlying illness~~disease~~ allows even a limited~~an~~ antibody response~~, even if limited~~.

In order to prevent hypersensitivity reactions, avoid administration in individuals~~administering the vaccine to persons~~ who have received a ~~complete~~ full primary vaccination or ~~a~~ booster dose within~~in~~ the previous 5 years.

In subjects who presented with ~~If~~ Guillain-Barré syndrome or brachial plexus neuropathy during the previous administration~~neuritis has occurred following receipt~~ of ~~prior~~ a vaccine containing tetanus toxoid, the decision to vaccinate with a~~give any~~ vaccine containing tetanus toxoid should be based on a careful evaluation~~consideration~~ of the potential risks and benefits ~~and possible risks~~. Vaccination is usually warranted~~justified~~ when the primary vaccination schedule is not complete (that is, less than~~immunisation schedules are incomplete (i.e., fewer than~~ three doses administered~~have been received~~).

Do not inject by ~~the~~ intravascular route~~. M~~: make sure the needle does not penetrate a blood vessel.

Syncope (fainting~~), a psychogenic reaction to an injection with a needle~~), ~~may~~ can occur following~~after~~, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should~~.~~

~~Measures must~~ be put in place~~implemented~~ to prevent any injury~~injuries~~ due to fainting~~,~~ and to manage syncopal reactions.

Imovax dT contains less than 1 mmol (39 mg) potassium, and less than 1 mmol (23 mg) sodium per dose, that is to say essentially “potassium-free” and “sodium-free”.

Traceability:

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

## ~~4.11~~4.5 Interaction with other medicinal products and other forms of interaction

No interactions~~There is no evidence of any interaction~~ with other medicinal products have been shown.

There ~~is~~ are no known disadvantages in administering~~contraindication to the administration of~~ this vaccine during the same~~a~~ vaccination session as the~~with~~ other usual~~common~~ vaccines.

## ~~4.12~~4.6 Pregnancy and lactation

**For diphtheria~~Diphtheria~~ vaccine**

There is no~~No~~ reliable data available on ~~animal~~ teratogenesis in animals~~data are available~~.

In clinical use~~Clinically~~, no specific malformative~~deformity~~ or fetotoxic effects have appeared~~been reported~~ to date. However~~–~~, the monitoring ~~follow up~~ of pregnancies~~pregnant women~~ exposed to the diphtheria vaccine is insufficient to exclude any~~rule out the~~ risk.

Because of the risk of ~~Since this vaccine may induce~~ hyperthermia, associated ~~a vaccine~~ with this vaccination, a ~~a~~ reduced ~~-~~valency vaccine ~~dose~~ should preferably be used in previously vaccinated pregnant women ~~who have been vaccinated previously~~.

**For tetanus~~Tetanus~~ vaccine**

Given~~Considering~~ the experimental and clinical data, this vaccine may be prescribed during ~~at any stage of~~ pregnancy if needed regardless of its term.

Therefore,~~Consequently and~~ as a precautionary measure, the use of~~precaution~~, this combination vaccine should~~is to~~ be avoided during pregnancy, unless the patient~~subject~~ is staying~~living~~ in or travelling to an epidemic~~endemic~~ area. If~~Should~~ one of the vaccines ~~be~~ is needed, it is recommended that a non-combination~~monovalent~~ vaccine ~~should be preferred.~~

~~There~~ is preferable~~no contraindication to vaccination during lactation~~.

Breast-feeding is not a contraindication.

## ~~4.13~~4.7 Effects on ability to drive and use machines

No studies on the~~The~~ effects on the ability to drive and use machines have ~~not~~ been performed~~studied~~.

## ~~4.14~~4.8 Undesirable effects

Based on data from spontaneous reports~~reporting~~, the following ~~adverse~~ events have been reported after~~during the commercial use of~~ Imovax dT was marketed. However, the~~, however~~ exact incidence ~~rates~~ cannot ~~precisely~~ be calculated precisely.

**Blood and lymphatic system disorders**

Lymphadenopathy.

**Immune system disorders**
Immediate hypersensitivity reactions such as face oedema, angio-oedema~~angioedema~~, Quincke’s oedema and anaphylactic reactions.

**Nervous system disorders**
Headache, feeling of~~Cephalalgia~~, malaise

**Vascular** disorders~~Disorders~~
Hypotension

**Skin and subcutaneous tissue disorders**
Pruritus, generalised ~~Generalised pruritus and~~ urticaria

Erythema or oedema

**Musculoskeletal and connective tissue disorders~~disorder~~**
Myalgia, arthralgia

**General disorders and administration site conditions~~condition~~**
Injection site reactions such as pain, rash, induration or oedema may~~can~~ occur within 48 hours and last~~persist~~ for ~~one~~ 1 or ~~two~~ 2 days. These reactions can sometimes be accompanied by a ~~with~~ subcutaneous nodule~~nodules~~. Cases of aseptic abscesses have been exceptionally ~~been~~ reported.

Temporary~~Transient~~ fever.

Malaise.

The majority of all~~All~~ these reactions were ~~have been~~ observed ~~more frequently~~ in hyperimmunized~~hyper immunised~~ subjects, particularly when~~in the case of over frequent~~ boosters were given too frequently.

**Potential undesirable effects~~adverse events~~**
(That is, they~~(i.e. adverse events which~~ have not been reported directly with Imovax dT~~,~~ but with other vaccines containing one or more of the antigenic constituents of Imovax dT): ~~Brachial neuritis and~~ Guillain-Barré syndrome and neuritis ~~Syndrome~~ after administration of a tetanus toxoid containing vaccine.

**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

### ~~4.15~~4.9 Overdose

Not documented.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**Pharmacotherapeutic group: bacterial vaccines, ATC code: J07 AM51.**

Immunity is enhanced from~~reinforced in~~ the days following the booster injection~~.~~ It ~~and~~ is generally accepted that it lasts between~~considered to last for~~ 5 and~~to~~ 10 years.

### 5.2 Pharmacokinetic properties

Not applicable.

### 5.3 Preclinical safety data

Non-clinical data reveal~~revealed~~ no special hazard for humans based on conventional studies of acute toxicity, repeated~~repeat~~ dose toxicity and local tolerability~~tolerance studies~~.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Acetic acid and/or sodium hydroxide for pH adjustment,

Buffer solution:

Sodium chloride,

Disodium phosphate dihydrate~~phosphate~~,

Monopotassium phosphate,

Hydrochloric acid and/or sodium hydroxide for pH adjustment~~,~~

Water for injections.

### 6.2 Incompatibilities

In the absence ofAs no compatibility studies are available, this medicinal product must not be mixed with other medicinal products.

### 6.3 Shelf life

The expiry date of the product is indicated on the packaging materials. After opening: the product should be used immediately.

### 6.4 Special precautions for storage

Store in a refrigerator (2°C-8°C). Do not freeze.

### 6.5 Nature and contents of container

0.5 ml of suspension in prefilled syringe (glass) fitted with a plunger stopper (bromobutyl or chlorobutyl) – box of 1 or 10.

### 6.6 Special precautions for disposal and other handling

Shake before injection, until a homogeneoushomogenous suspension is obtained before injection.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

## 7 MANUFACTURER:

SANOFI PASTEUR
14 Espace Henry Vallée
69007 Lyon, France

## 87 LICENSE MARKETING AUTHORISATION HOLDER

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

## 98 MARKETING AUTHORISATION NUMBERS

144-62-33232-00

The content of this leaflet was approved by the Ministry of Health in May 2012 and updated according to the guidelines of the Ministry of Health in Feb 2023. Revised in December 2023 according to MoH's guidelines.