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 IU

Tetanus toxoid .....≥ 20 IU

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

For one dose of 0.5 ml.

For 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

Dosage

- For routine boosters, a single dose of 0.5 ml should be givenevery 10 years.
- For primary vaccination, 3 successive doses of 0.5 ml should be administered 1 month apart..
- For prophylaxis in people exposed to a risk of tetanus, the following recommended schedule should be followed:

TYPE OF INJURY	PATIENT NOT IMMUNISED OR VACCINATION INCOMPLETE	PATIENT FULLY IMMUNISED Time since last booster	
		5 to 10 years	>10 years
Minor – clean	**Start or complete vaccination: Tetanus toxoid 1 dose of 0.5 ml**	**No injection**	**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.
**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 (IM) in order to minimise local reactions. The recommended sites are: the anterolateral aspect of the thigh or arm.

Deep subcutaneous (SC) injection may also be used.

However, intradermal injection should not be used.

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

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 and to formaldehyde (which may be present in trace amounts due to its use during manufacturing).
- In cases of fever, acute, particularly infectious, illness or chronic illness during an active phase, it is preferable to postpone vaccination unless there is an absolute indication, such as 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.

4.4 Special warnings and precautions for use

As with any injectable vaccine, appropriate medical treatment should be readily available and the patient should be closely monitored if an anaphylactic reaction occurs after the administration of the vaccine.

Immunosuppressivetreatment or an immunodeficiency condition may induce a decrease in the immune response to the vaccine. It is therefore recommended to wait untilthe end of treatment before vaccinating or to ensure that the subject is well protected. Nevertheless, the vaccination of chronically immunosuppressed subjects, such those infected with HIV, is recommended if the underlying illnessallows even a limitedantibody response.

In order to prevent hypersensitivity reactions, avoid administration in individuals who have received a full primary vaccination or booster dose withinthe previous 5 years.

In subjects who presented with Guillain-Barré syndrome or brachial plexus neuropathy during the previous administration of a vaccine containing tetanus toxoid, the decision to vaccinate with a vaccine containing tetanus toxoid should be based on a careful evaluation of the potential risks and benefits. Vaccination is usually warranted when the primary vaccination schedule is not complete (that is, less than three doses administered).

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

Syncope (fainting), can occur following, or even before, any vaccination as a psychogenic response to the needle injection. Procedures should be put in placeto prevent any injurydue 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 of the administered product should be clearly recorded. It is recommended to record the batch number as well.

4.5 Interaction with other medicinal products and other forms of interaction

No interactionswith other medicinal products have been shown.

There are no known disadvantages in administering this vaccine during the samevaccination session as theother usualvaccines.

4.6 Pregnancy and lactation

For diphtheriavaccine

There is noreliable data available on teratogenesis in animals.

In clinical use, no specific malformativeor fetotoxic effects have appeared to date. However, the monitoring of pregnancies exposed to the diphtheria vaccine is insufficient to exclude any risk.

Because of the risk of hyperthermia, associated with this vaccination, a reduced -valency vaccine should preferably be used in previously vaccinated pregnant women.

For tetanusvaccine

Giventhe experimental and clinical data, this vaccine may be prescribed during pregnancy if needed regardless of its term.

Therefore,as a precautionary measure, the use of, this combination vaccine should be avoided during pregnancy, unless the patient is stayingin or travelling to an epidemicarea. Ifone of the vaccines is needed, it is recommended that a non-combinationvaccine is preferable.

Breast-feeding is not a contraindication.

4.7 Effects on ability to drive and use machines

No studies on theeffects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Based on data from spontaneous reports, the following events have been reported after Imovax dT was marketed. However, the exact incidence cannot be calculated precisely.

Blood and lymphatic system disorders

Lymphadenopathy.

Immune system disorders
Immediate hypersensitivity reactions such as face oedema, angio-oedema, Quincke's oedema and anaphylactic reactions.

Nervous system disorders
Headache, feeling of, malaise

Vascular disorders
Hypotension

Skin and subcutaneous tissue disorders
Pruritus, generalised urticaria

Erythema or oedema

Musculoskeletal and connective tissue disorders
Myalgia, arthralgia

General disorders and administration site conditions
Injection site reactions such as pain, rash, induration or oedema mayoccur within 48 hours and lastfor 1 or 2 days. These reactions can sometimes be accompanied by a subcutaneous nodule. Cases of aseptic abscesses have been exceptionally reported.

Temporaryfever.

Malaise.

The majority of allthese reactions were observed in hyperimmunized subjects, particularly when boosters were given too frequently.

Potential undesirable effects

(That is, they have not been reported directly with Imovax dT but with other vaccines containing one or more of the antigenic constituents of Imovax dT): Guillain-Barré syndrome and neuritis 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

4.9 Overdose

Not documented.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Immunity is enhanced from the days following the booster injection. It is generally accepted that it lasts between 5 and10 years.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Non-clinical data revealno special hazard for humans based on conventional studies of acute toxicity, repeateddose toxicity and local tolerability.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetic acid and/or sodium hydroxide for pH adjustment,

Buffer solution:

Sodium chloride,

Disodium phosphate dihydrate,

Monopotassium phosphate,

Hydrochloric acid and/or sodium hydroxide for pH adjustment

Water for injections.

6.2 Incompatibilities

In the absence of compatibility studies, 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 until a homogeneous suspension is obtained before injection.

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

8 MARKETING AUTHORISATION NUMBER

144-62-33232-00

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