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 0.5-ml dose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection in 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

- For routine booster injections, a single dose of 0.5 ml should be administered every 10 years.
- For primary vaccination, 3 successive 0.5 ml doses should be administered at monthly intervals.
- The post–tetanus exposure prophylaxis recommendations are summarized below:

TYPE OF WOUND	**PATIENT NOT IMMUNISED OR PARTIALLY IMMUNISED**	**PATIENT COMPLETELY IMMUNISED Time since last booster dose**	
		5 to 10 years	**>10 years**
Minor – clean	Begin or complete vaccination: Tetanus toxoid, 1 dose of 0.5 ml	None	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 the vaccination according to the vaccination schedule.

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

The deep sub-cutaneous (SC) route may also be used.

However, the intradermal route must not be used.

(See Instructions for use, handling and disposal - Section 6.6).

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1, or to formaldehyde (which may be present as traces owing to its use during the manufacturing process).
- 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 a lethal risk associated with a tetanus-prone wound.
- Hypersensitivity reaction or neurological disorder after a previous injection of vaccine.

4.4 Special warnings and precautions for use

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

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

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

If Guillain-Barré syndrome or brachial neuritis has occurred following receipt of prior vaccine containing tetanus toxoid, the decision to give any vaccine containing tetanus toxoid should be based on careful consideration of the potential benefits and possible risks. Vaccination is usually justified when primary immunisation schedules are incomplete (i.e., fewer than three doses have been received).

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

4.5 Interaction with other medicinal products and other forms of interaction

There is no evidence of any interaction with other medicinal products.

There is no contraindication to the administration of this vaccine during a vaccination session with other common vaccines.

4.6 Pregnancy and lactation

Diphtheria vaccine

No reliable animal teratogenesis data are available.
Clinically, no deformity or fetotoxic effects have been reported to date. However follow up of pregnant women exposed to the diphtheria vaccine is insufficient to rule out the risk.

Since this vaccine may induce hyperthermia, a vaccine with a reduced dose should be used in pregnant women who have been vaccinated previously.

Tetanus vaccine

Considering the experimental and clinical data, this vaccine may be prescribed at any stage of pregnancy if needed.

Consequently and as a precaution, this combination is to be avoided during pregnancy unless the subject is living in or travelling to an endemic area. Should one of the vaccines be needed, a monovalent vaccine should be preferred.

There is no contraindication to vaccination during lactation.

4.7 Effects on ability to drive and use machines

The effects on the ability to drive and use machines have not been studied.

4.8 Undesirable effects

Based on spontaneous reporting, the following adverse events have been reported during the commercial use of Imovax dT, however exact incidence rates cannot precisely be calculated.

Blood and lymphatic system disorders

Lymphadenopathy

Immune system disorders

Immediate hypersensitivity reactions such as face oedema, angioedema, Quincke's oedema and anaphylactic reactions.

Nervous system disorders
Cephalalgia, malaise

Vascular Disorders
Hypotension

Skin and subcutaneous tissue disorders
Generalised pruritus and urticaria

Erythema or oedema

Musculoskeletal and connective tissue disorder
Myalgia, arthralgia

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

Transient fever.

Malaise.

All these reactions have been observed more frequently in hyper immunised subjects, particularly in the case of over-frequent boosters.

Potential adverse events

(i.e. adverse events which have not been reported directly with Imovax dT, but with other vaccines containing one or more of the constituents of Imovax dT): Brachial neuritis and Guillain-Barré 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

4.9 Overdose

Not documented.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Immunity is reinforced in the days following the booster injection and is generally considered to last for 5 to 10 years.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Buffer solution containing sodium chloride, disodium dihydrate phosphate, monopotassium phosphate and water for injections.

6.2 Incompatibilities

As 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) with a plunger stopper (bromobutyl or chlorobutyl or bromochlorobutyl) – box of 1 or 10.

6.6 Instructions for use, handling and disposal

Shake before injection, until a homogenous suspension is obtained.
Any unused product or waste material should be disposed of in accordance with local requirements

7 MANUFACTURER:

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8 LICENSE HOLDER

Medici Medical Ltd, 3 Hamachshev St. Netanya 4250713, Israel

9 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 March 2020.