



August 2025

רופא/ה, רוקח/ת נכבד/ה,

הנדון: Qdenga

חברת טקדה ישראל בע"מ מבקשת להודיעכם על עדכונים בעלון לרופא של התכשיר שבנדון:

ההתוויות להן רשום התכשיר:

Qdenga is indicated for the prevention of dengue disease in individuals from 4 years of age

צורת מינון: Powder and solvent for solution for injection

מרכיב פעיל:

DENGUE VIRUS SEROTYPE 4 (LIVE, ATTENUATED) (NLT 4.5 log₁₀ PFU/VIAL)
DENGUE VIRUS SEROTYPE 3 (LIVE, ATTENUATED) (NLT 4.0 log₁₀ PFU/VIAL)
DENGUE VIRUS, SEROTYPE 2, LIVE, ATTENUATED) (NLT 2.7 log₁₀ PFU/VIAL)
DENGUE VIRUS SEROTYPE 1 (LIVE, ATTENUATED) (NLT 3.3 log₁₀ PFU/VIAL)

פרטי העדכונים העיקריים מופיעים בהמשך (טקסט שנוסף מסומן **בכחול**, טקסט שהושמט מסומן **אדום עם קו-חוצה**, טקסט המהווה החמרה מודגש **בצהוב**), אך קיימים עדכונים נוספים.

עלון לרופא:

4.3 Contraindications

- Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 or hypersensitivity to a previous dose of Qdenga.
- Individuals with congenital or acquired immune deficiency, including [those receiving immunosuppressive therapies such as ~~Chemotherapy or~~ high doses of systemic corticosteroids \(e.g. 20 mg/day or 2 mg/kg body weight/day of prednisone for 2 weeks or more\) within 4 weeks prior to vaccination, \[or any other medicinal product with known immunosuppressive properties including chemotherapy as with other live attenuated vaccines.\]\(#\) \[The time to avoid vaccination after immunosuppressive treatment should be considered on an individual basis.\]\(#\)](#)

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4.5 Interaction with other medicinal products and other forms of interaction

For patients receiving treatment with immunoglobulins or blood products containing immunoglobulins, such as blood or plasma, it is recommended to wait for at least 6 weeks, and preferably for 3 months, following the end of treatment before administering Qdenga, in order to avoid neutralisation of the attenuated viruses contained in the vaccine.

Qdenga should not be administered to subjects receiving immunosuppressive therapies such

Takeda Israel Ltd.

25 Efal st., P.O.B 4140, Petach-Tikva 4951125

Tel: +972-3-33733140 Fax (local) : + 972-3-3733150



as ~~Chemotherapy~~ or high doses of systemic corticosteroids within 4 weeks prior to vaccination, or any other medicinal product with known immunosuppressive properties including chemotherapy (see section 4.3). The time to avoid vaccination after immunosuppressive treatment should be considered on an individual basis.

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4.8 Undesirable effects

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Table 1: Adverse reactions from clinical studies (age 4 to 60 years) and post-authorisation experience (age 4 years and older)

MedDRA System Organ Class	Frequency	Adverse Reactions
Infections and infestations	Very common	Upper respiratory tract infection ^a
	Common	Nasopharyngitis Pharyngotonsillitis ^b
	Uncommon	Bronchitis Rhinitis
<u>Blood and lymphatic system disorders</u>	<u>Very rare</u>	<u>Thrombocytopenia^c</u>
Immune system disorders	Not known	Anaphylactic reaction, including anaphylactic shock ^c
Metabolism and nutrition disorders	Very common	Decreased appetite ^d
Psychiatric disorders	Very common	Irritability ^d
Nervous system disorders	Very common	Headache Somnolence ^d
	Uncommon	Dizziness
<u>Eye disorders</u>	<u>Not known</u>	<u>Eye pain^e</u>
Gastrointestinal disorders	Uncommon	Diarrhoea Nausea Abdominal pain Vomiting
Skin and subcutaneous tissue disorders	Uncommon	Rash ^e Pruritus ^f Urticaria
	Rare	Petechiae ^e
	Very rare	Angioedema
Musculoskeletal and connective tissue disorders	Very common	Myalgia
	Common	Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Injection site erythema Malaise Asthenia Fever
	Common	Injection site swelling Injection site bruising ^f Injection site pruritus ^f Influenza like illness



MedDRA System Organ Class	Frequency	Adverse Reactions
	Uncommon	Injection site haemorrhage ^f Fatigue ^f Injection site discolouration ^f

6.6 Special precautions for disposal and other handling

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Remove the vaccine and solvent vials from the refrigerator ~~and place at room temperature for approximately 15 minutes.~~

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות.

כמו כן, מצורף לפרסום זה וניתן לקבל העתק מודפס שלו באמצעות פנייה לבעל הרישום:

טקדה ישראל בע"מ, רח' אפעל 25, פתח-תקווה, טל': 03-3733140.

בברכה,

נטע ברונשטיין, רוקחת ממונה
טקדה ישראל בע"מ