November 2024

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 כטקסט ~~אדום עם קו חוצה~~, טקסט המהווה החמרה מודגש בצהוב*), אך קיימים עדכונים נוספים.

עלון לרופא:

4.4 Special warnings and precautions for use

General recommendations

Anaphylaxis

Anaphylaxis has been reported in individuals who have received Qdenga. As with all injectable vaccines, appropriate medical treatment and supervision must always be readily available in the event of a rare anaphylactic reaction following administration of the vaccine.

…

4.5 Interaction with other medicinal products and other forms of interaction

Qdenga may be administered concomitantly with a human papillomavirus (HPV) vaccine (see section 5.1).

Takeda Israel Ltd.
25 Efal st., P.O.B 4140, Petach-Tikva 4951125
Tel:+972--3-33733140 Fax (local) : + 972-3-3733150

4.8 Undesirable effects

Tabulated list of adverse reactions

Adverse reactions associated with Qdenga obtained from clinical studies and post-authorisation experience are tabulated below (**Table 1**).

The safety profile presented below is based on ~~a~~ data generated in placebo-controlled clinical studies and post-authorisation experience. ~~pooled~~ Pooled analysis ~~including~~ of clinical studies included data from 14,627 study participants aged 4 to 60 years (13,839 children and 788 adults) who have been vaccinated with Qdenga. This included a reactogenicity subset of 3,830 participants (3,042 children and 788 adults).

Adverse reactions are listed according to the following frequency categories:
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 the available data

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
…		
Immune system disorders	Not known	Anaphylactic reaction, including anaphylactic shock[C]
…		

[C] Adverse reaction observed post-authorisation

…

5.1 Pharmacodynamic properties

…

Co-administration with HPV

In study DEN-308 involving approximately 300 subjects aged 9 to 14 years who received Qdenga concomitantly with a 9-valent HPV vaccine, there was no effect on the immune response to the HPV vaccine. The study only tested co-administration of the first doses of Qdenga and the 9-valent HPV vaccine. Non-inferiority of the Qdenga immune response, when Qdenga and the 9-valent HPV vaccine were co-administered, has not been directly assessed in the study. In the dengue seronegative study population, dengue antibody responses after co-administration were in the same range as those observed in the Phase 3 study (DEN-301) where efficacy against VCD and hospitalised VCD was shown.

Takeda Israel Ltd.
25 Efal st., P.O.B 4140, Petach-Tikva 4951125
Tel:+972--3-33733140 Fax (local) : + 972-3-3733150

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות.

כמו כן, מצורפים לפרסום זה וניתן לקבל העתק מודפס שלהם 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

Takeda Israel Ltd.
25 Efal st., P.O.B 4140, Petach-Tikva 4951125
Tel:+972--3-33733140 Fax (local) : + 972-3-3733150