Dengue Vaccine Live

AHFS Class: 80:12 — Vaccines (tofc-80)

Dengue Vaccine Live *(AHFS DI)*

Chimeric Yellow Fever Dengue Virus Serotype 1 Live (attenuated) Antigen **Chimeric Yellow Fever Dengue Virus Serotype 2 Live (attenuated) Antigen** **Chimeric Yellow Fever Dengue Virus Serotype 3 Live (attenuated) Antigen** **Chimeric Yellow Fever Dengue Virus Serotype 4 Live (attenuated) Antigen**

Brands: Dengvaxia®

Introduction

Dengue vaccine live is a live, attenuated virus vaccine.[1,]

Uses

▪ Dengue vaccine live has the following uses:

Dengue vaccine live is indicated for the prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4. Dengue vaccine live is approved for use in individuals 6 through 16 years of age with laboratory-confirmed previous dengue infection and living in endemic areas.[1,]

Dengue vaccine live is not approved for use in individuals younger than 6 years of age. These individuals, regardless of previous infection by dengue virus, are at increased risk of severe and hospitalized dengue disease following vaccination with dengue vaccine live and subsequent infection with any dengue virus serotype.

Dengue vaccine live is not approved for use in individuals not previously infected by any dengue virus serotype or for whom this information is unknown. Those not previously infected are at increased risk for severe dengue disease when vaccinated and subsequently infected with dengue virus. Previous dengue infection can be assessed through a medical record of a previous laboratory-confirmed dengue infection or through serological testing prior to vaccination.[1,]

The safety and effectiveness of dengue vaccine live have not been established in individuals living in dengue nonendemic areas who travel to dengue endemic areas.[1,]

Dosage and Administration

▪ General

Dengue vaccine live is available in the following dosage form(s) and strength(s):

Suspension for injection (0.5 mL) supplied as a lyophilized powder to be reconstituted with the supplied diluent.[1,]

▪ Dosage

It is *essential* that the manufacturer's labeling be consulted for more detailed information on dosage and administration of this drug. Dosage summary:

Pediatric Patients

Three doses (0.5 mL each) 6 months apart (at month 0, 6, and 12).[1,]

Cautions

▪ Contraindications

A history of severe allergic reaction to a previous dose of dengue vaccine live or to any component of dengue vaccine live.[1,]

Immunocompromised individuals.[1,]

▪ Warnings/Precautions

Increased Risk of Severe Dengue Disease Following Dengue Vaccine Live in Persons Younger than 6 Years of Age Regardless of Previous Infection with Dengue Virus

Dengue vaccine live is not approved for use in individuals younger than 6 years of age.[1,] In persons younger than 6 years of age regardless of previous infection by dengue virus, an increased risk of severe and hospitalized dengue disease can occur following vaccination with dengue vaccine live and subsequent infection with any dengue virus serotype.[1,]

Increased Risk of Severe Dengue Disease Following Dengue Vaccine Live in Persons of Any Age Not Previously Infected with Dengue Virus

In unvaccinated individuals, first dengue infections rarely cause severe dengue disease, while second dengue infections with a different serotype are associated with an increased risk of severe dengue disease. Dengue vaccine live administration to individuals not previously infected by dengue virus is associated with an increased risk of severe dengue disease when the vaccinated individual is subsequently infected with any dengue virus serotype. Therefore, healthcare professionals must evaluate individuals for prior dengue infection to avoid vaccinating individuals who have not been previously infected by dengue virus.[1,]

Previous infection by dengue virus can be evaluated through a medical record of previous laboratory-confirmed dengue infection or through serotesting prior to vaccination.[1,]

There is no FDA cleared test available to determine a previous dengue infection. Available non-FDA cleared tests may yield false positive results (e.g., due to cross-reactivity with other flaviviruses).[1,]

Management Of Acute Allergic Reactions

Dengue vaccine live may cause hypersensitivity reactions, including anaphylaxis. Appropriate medical treatment and supervision must be available following administration of dengue vaccine live.[1,]

Limitations of Vaccine Effectiveness

Vaccination with dengue vaccine live may not protect all individuals. It is recommended to continue personal protection measures against mosquito bites after vaccination.[1,]

Syncope

Syncope (fainting) can occur following, or even before, vaccination with dengue vaccine live as a psychogenic response to injection with a needle. Procedures should be in place to prevent injury from falling and to manage syncopal reactions.[1,]

Specific Populations

Pregnancy.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to dengue vaccine live during pregnancy. Women who receive dengue vaccine live during pregnancy are encouraged to contact directly, or have their healthcare professional contact, Sanofi Pasteur Inc. at 1-800-822-2463 (1-800-VACCINE) to enroll in or obtain information about the registry.[1,]

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.[1,]

No specific studies of dengue vaccine live have been performed among pregnant women. A limited number of cases of inadvertent exposure during pregnancy were reported during clinical studies. Isolated adverse pregnancy outcomes (e.g., stillbirth, intrauterine death, spontaneous abortion, blighted ovum) have been observed for these exposed pregnancies, with similar frequency and nature in the vaccinated individuals compared to the control group, and with risk factors identified for all cases. Available data in pregnant women are not sufficient to determine the effects of dengue vaccine live on pregnancy, embryo-fetal development, parturition and postnatal development.[1,]

In two developmental toxicity studies, the effect of dengue vaccine live on embryo-fetal and postnatal development was evaluated in pregnant rabbits and mice. A developmental toxicity study was performed in female rabbits given a 5 $\log_{10}$ 50% cell culture infectious dose ($CCID_{50}$) of dengue vaccine live (full human dose ranging from 4.5 $\log_{10}$ to 6.0 $\log_{10}$ $CCID_{50}$) by intravenous injection prior to mating and during gestation. The study revealed no evidence of harm to the fetus due to dengue vaccine live. In another study, female mice were administered a single dose of 5 log $CCID_{50}$, 6.5 log $CCID_{50}$ (about 3 times the highest human dose) or 8 $\log_{10}$ $CCID_{50}$ (about 100 times the highest human dose) of dengue vaccine live by intravenous injection during gestation. Fetal toxicities were observed at maternally toxic doses.[1,]

Pregnant women are at increased risk of complications associated with dengue infection compared to non-pregnant women. Pregnant women with dengue infection may be at increased risk for adverse pregnancy outcomes, including preterm labor and delivery. Vertical transmission of dengue virus from mothers with viremia at delivery to their infants has been reported.[1,]

Vaccine viremia can occur 7 to 14 days after vaccination with a duration of <7 days. The potential for transmission of the vaccine virus from mother to infant is unknown.[1,]

Lactation.

Risk Summary: Human data are not available to assess the impact of dengue vaccine live on milk production, its presence in breast milk, or its effects on the breastfed child. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for dengue vaccine live and any potential adverse effects on the breastfed child from dengue vaccine live or from the underlying maternal condition. For preventive vaccines, the underlying condition is susceptibility to disease prevented by the vaccine. A lactation study in which female mice were administered a single dose of dengue vaccine live on day 14 of lactation did not show the presence of dengue vaccine live in breast milk.[1,]

Vaccine viremia can occur 7 to 14 days after vaccination with a duration of <7 days. The potential for transmission of the vaccine virus from mother to infant through breastmilk is unknown.[1,]

Pediatric Use.

Dengue vaccine live is not approved for use in individuals younger than 6 years of age. Evidence from clinical studies strongly suggests that dengue vaccine live would be unsafe in individuals younger than 6 years of age because of an increased risk of severe and hospitalized dengue regardless of dengue serostatus.[1,]

Geriatric Use.

Safety and effectiveness of dengue vaccine live in adults 65 years of age and older have not been established.[1,]

▪ Common Adverse Effects

The most frequently reported adverse reactions regardless of the dengue serostatus prior to vaccination in ages 9 through 16 years were headache (40%), injection site pain (32%), malaise (25%), asthenia (25%), and myalgia (29%).[1,]

The most frequently reported adverse reactions regardless of the dengue serostatus prior to vaccination in ages 6 through 8 years were headache (27%), injection site pain (28%), malaise (19%), asthenia (13%), and myalgia (15%).[1,]

Drug Interactions

▪ Specific Drugs

It is *essential* that the manufacturer's labeling be consulted for more detailed information on interactions with this drug, including possible dosage adjustments. Interaction highlights:

False negative tuberculin purified protein derivative (PPD) test results may occur within 1 month following vaccination with dengue vaccine live.[1,]

Actions

▪ Mechanism of Action

Following administration, dengue vaccine live elicits dengue-specific immune responses against the four dengue virus serotypes. The exact mechanism of protection has not been determined.[1,]

Advice to Patients

The following information contains important points for the clinician to discuss with patients during counseling. For more comprehensive monographs suitable for distribution to the patient, please refer to the *AHFS Patient Medication Information* monographs available from MedlinePlus (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus) (in English and Spanish; written at a 6th- to 8th-grade reading level).

Educate vaccine recipients regarding the most common adverse reactions that occur within 14 days following administration of dengue vaccine live (headache, injection site pain, malaise, asthenia, and myalgia).[1,]

Inform individuals to seek medical care if they develop signs and symptoms of dengue fever with particular attention to severe dengue warning signs (e.g., high fever, severe abdominal pain or tenderness, persistent vomiting, mucosal bleeding, somnolence and hyperactivity).[1,]

Register women who receive dengue vaccine live during pregnancy in the Pregnancy Registry by calling 1-800-822- 2463 (1-800-VACCINE).[1,]

Instruct vaccine recipients to report adverse reactions to their healthcare provider.[1,]

Additional Information

AHFS*first*Release™. For additional information until a more detailed monograph is developed and published, the manufacturer's labeling should be consulted. It is *essential* that the manufacturer's labeling be consulted for more detailed information on usual uses, dosage and administration, cautions, precautions, contraindications, potential drug interactions, laboratory test interferences, and acute toxicity.

Photos

Disclaimer (https://pillbox.nlm.nih.gov/about.html)

Preparations

Excipients in commercially available drug preparations may have clinically important effects in some individuals; consult specific product labeling for details.

Dengue Vaccine Live (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Dengue+Vaccine+Live&collapse=1)

Parenteral

For Injection, for subcutaneous use

4.5–6 $\log_{10}$ $CCID_{50}$ (50% cell culture infectious dose) each of chimeric yellow fever dengue (CYD) virus serotypes 1, 2, 3, and 4 per 0.5 mL

Dengvaxia®, Sanofi Pasteur (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=LabelerName&ApptName=Sanofi+Pasteur&collapse=1)

Related Resources

AHFS Patient Medication Information (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus&query=Dengue%20Vaccine%20Live) and other related patient health topics (MedlinePlus)
ASHP Drug Shortages Resource Center (https://www.ashp.org/Drug-Shortages)
CCRIS (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+ccris:%%22Dengue%20Vaccine%20Live%%22) (Chemical Carcinogenesis Research Information System)
ChemID*plus* (https://chem.nlm.nih.gov/chemidplus/name/Dengue%20Vaccine%20Live)
Biochemical Data Summary (http://www.drugbank.ca/unearth/q?utf8=%%E2%%9C%%93&query=Dengue%20Vaccine%20Live&searcher=drugs&approved=1&vet_approved=1&nutraceutical=1&illicit=1&withdrawn=1&investi (US and Canada)
Clinical Trials (https://www.clinicaltrials.gov/ct/search?submit=Search&term=Dengue%20Vaccine%20Live)
DailyMed (https://dailymed.nlm.nih.gov/dailymed/search.cfm?query=Dengue%20Vaccine%20Live) (drug labels)
DART (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+dart:%%22Dengue%20Vaccine%20Live%%22) (Developmental and Reproductive Toxicology Database)
Drugs@FDA (https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchType=BasicSearch&SearchTerm=Dengue%20Vaccine%20Live) (approval information)
European Medicines Agency (https://www.ema.europa.eu/en/search/search?search_api_views_fulltext=Dengue%20Vaccine%20Live)
FDA National Drug Code Directory (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Dengue%20Vaccine%20Live&collapse=1)
FDA Recalls, Market Withdrawals, and Safety Alerts (https://www.fda.gov/Safety/Recalls/default.htm)
HSDB (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:%%22Dengue%20Vaccine%20Live%%22) (Hazardous Substances Data Bank)
Inxight Drugs (https://drugs.ncats.io/substances?q=%%22Dengue%20Vaccine%20Live%%22) (National Center for Advancing Translational Sciences)
LactMed (drug effects on breastfeeding) (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+lactmed:@or+%%28@na+%%22Dengue%20Vaccine%20Live%%22+%%29)
New Drug Approvals (https://ahfs.ashp.org/drug-assignments.aspx)
Orange Book (https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm?panel=0&drugname=Dengue%20Vaccine%20Live) (therapeutic equivalence)
PharmGKB (https://www.pharmgkb.org/search?connections&gaSearch=Dengue%20Vaccine%20Live&query=Dengue%20Vaccine%20Live&type=chemical) (Pharmacogenomic data from PharmGKB)
Pillbox (*beta*) (https://pillbox.nlm.nih.gov/pillimage/search_results.php?submit=Search&splid=&getingredient=Dengue%20Vaccine%20Live) (drug identification and images)
PubMed (https://www.ncbi.nlm.nih.gov/pubmed?DB=pubmed&term=Dengue%20Vaccine%20Live%%5BAll+Fields%%5D) (scientific journals)
Safety-related Labeling Changes (https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges) (FDA/CDER)
ToxLine (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+toxline:%%22Dengue%20Vaccine%20Live%%22) (Toxicology Literature Online)

† Use is not currently included in the labeling approved by the US Food and Drug Administration.

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References

1. Sanofi Pasteur Inc. DENGVAXIA® (Dengue Tetravalent Vaccine, Live) prescribing information. 2023 Jul.[Web] (http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=280ee057-3488-4d77-b510-8bc733eeca1e)

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