Chikungunya Vaccine, Recombinant

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

Chikungunya Vaccine, Recombinant *(AHFS DI)*

Introduction

Chikungunya vaccine (recombinant) is a recombinant vaccine containing purified virus-like particles (VLPs) consisting of chikungunya virus (CHIKV) capsid protein (C) and envelope proteins E1 and E2, derived from CHIKV Senegal strain 37997.[1,5]

Uses

▪ Prevention of Chikungunya Virus

Chikungunya vaccine (recombinant) is used for the prevention of disease caused by chikungunya virus (CHIKV) in individuals 12 years of age or older.[1,5]

This indication is approved under accelerated approval based on anti-CHIKV neutralizing antibody levels.[1] Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial.[1]

Clinical Experience

The accelerated approval and current indication for chikungunya vaccine (recombinant) for prevention of chikungunya virus (CHIKV) are based principally on data from two phase 3, randomized, placebo-controlled, double-blind, parallel-group studies.[1,6,7,3] In both studies, effectiveness of the vaccine was assessed by the seroresponse rate (defined as the proportion of patients who achieved 80% serum neutralizing antibody titre [NT_{80}] of ≥100) at Day 22 and serum neutralizing antibody (SNA) geometric mean titre (GMT) at Day 22.[1,3,5,6,7] A key secondary endpoint was the difference in CHIKV SNA seroresponse rate on Day 183.[6,7] The first study included healthy adolescents and adults 12–64 years of age.[1,3,5] Participants were randomized to receive a single dose of chikungunya vaccine (recombinant) or placebo.[3,6,5] Vaccine recipients were assessed during on-site study visits for safety and immunogenicity on days 8, 15, 22, and 183 following vaccination.[6] The immunogenicity evaluable population included a total of 2559 individuals who received a single dose of chikungunya vaccine (recombinant) and 424 individuals who received placebo.[6] At Day 22, the seroresponse rate was 97.8% in subjects who received the vaccine compared with a seroresponse rate of 1.2% in the placebo group, for a seroresponse rate difference of 96.6%.[1,3,6,5] On Day 22, SNA GMT was 1597 for the chikungunya vaccine (recombinant) group and 7.9 for the placebo group, resulting in a GMT ratio of 203.[1,5] On Day 183, the seroresponse rate for the chikungunya vaccine (recombinant) group was 85.5% compared to 1.5% in the placebo group (difference in seroresponse rate of 84%).[1,6] The durability of antibody response was demonstrated up to 6 months after vaccination with a seroresponse rate of 85.5% on Day 183.[6]

The second study enrolled healthy adults ≥65 years of age; patients were randomly assigned to receive either chikungunya vaccine (recombinant) or placebo.[1,7,5] The immunogenicity evaluable population included 372 individuals (189 in the chikungunya vaccine group and 183 in the placebo group).[7] On Day 22, the seroresponse rate in the chikungunya vaccine (recombinant) group was 87.3% compared to 1.1% in the placebo group (difference of 86%).[1,3,7,5] On Day 22, the SNA GMT was 721 in the vaccine group and 8 in the placebo group, resulting in a GMT ratio of 89.2.[1,5] On Day 183, the seroresponse rate was 75.5% in the chikungunya vaccine (recombinant) group and 1.2% in the placebo group (seroresponse rate difference of 74.4%).[1,7]

Clinical Perspective

Chikungunya virus (CHIKV) is a mosquito-borne alphavirus of the Togaviridae family.[8,9,10] CHIKV infection may present with fever, rigors, rash, and joint pain and less frequently, result in severe polyarthralgia and arthritis.[8,9,10] Infections caused by CHIKV may be self-limited with the acute phase resolving in 3-4 days, but some patients develop persistent joint pain lasting months to years after initial infection.[8,9] Persistent arthralgia is more likely to occur in patients >60 years of age with a higher viral load during the acute phase of the disease.[8] Severe forms of chikungunya viral infection involve the CNS or cause fulminant hepatitis.[9] Vertical chikungunya viral infection (mother-to-child transmission) has been reported during CHIKV outbreaks.[8]

The risk of chikungunya for most US travelers is low; however, some travelers may be at higher risk for infection based on their destination or duration of travel.[11] The Centers for Disease Control and Prevention (CDC) provide recommendations for chikungunya vaccination in US travelers.[11] Chikungunya vaccine is recommended for those traveling to a country or territory where a chikungunya outbreak is occurring.[11] CDC state that the vaccine may also be considered for individuals traveling or moving to a country or territory without an outbreak but with elevated risk if they are planning to stay for an extended period (e.g., 6 months or more).[11] CDC also recommend the chikungunya vaccine for laboratory workers with potential exposure to the vaccine.[11]

Dosage and Administration

▪ General

Dispensing and Administration Precautions

Appropriate treatment must be available during administration to manage immediate allergic reactions.[1]

Because syncope can occur during administration of the vaccine, procedures should be in place to avoid injury from fainting.[1]

▪ Administration

Administer chikungunya vaccine (recombinant) by IM injection.[1]

The vaccine is supplied as a prefilled syringe containing a single dose of 0.8 mL.[1]

Shake the prefilled syringe vigorously immediately before use to form a homogeneous suspension.[1] After shaking, the suspension should be a white, cloudy liquid.[1]

Visually inspect product for particulate matter and discoloration prior to administration, whenever solution and container permit.[1] Discard if either condition is present.[1]

Store chikungunya vaccine (recombinant) in a refrigerator at 2–8°C in the original carton to protect from light.[1] Do not freeze.[1] The vaccine may be stored at room temperature (up to 25°C) for up to 2 hours after removal from refrigerator.[1] Discard the vaccine if not used within 2 hours after removal from refrigerator.[1]

▪ Dosage

Prevention of Disease Caused by Chikungunya Virus

The recommended dose of chikungunya vaccine (recombinant) for the prevention of disease caused by CHIKV in individuals 12 years of age and older is a single 0.8 mL IM injection.[1]

▪ Special Populations

Hepatic Impairment

The manufacturer makes no specific dosage recommendation for individuals with hepatic impairment.[1]

Renal Impairment

The manufacturer makes no specific dosage recommendation for individuals with renal impairment.[1]

Geriatric Patients

The manufacturer makes no specific dosage recommendation for geriatric individuals.[1]

Cautions

▪ Contraindications

History of a severe allergic reaction (e.g., anaphylaxis) to any component of chikungunya vaccine (recombinant).[1]

▪ Warnings/Precautions

Management of Allergic Reactions

Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of chikungunya vaccine (recombinant).[1]

Altered Immunocompetence

Immunocompromised individuals, including individuals receiving immunosuppressive therapy, may have a diminished immune response to chikungunya vaccine (recombinant).[1]

Syncope

Syncope (fainting) may occur with administration of injectable vaccines, including chikungunya vaccine (recombinant).[1] Procedures should be in place to avoid injury from fainting.[1]

Specific Populations

Pregnancy.

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to chikungunya vaccine (recombinant) during pregnancy.[1] Women who receive chikungunya vaccine (recombinant) during pregnancy are encouraged to contact, or have their healthcare provider contact, 1-888-230-2491 to enroll in or obtain information about the registry.[1]

There are no clinical studies of chikungunya vaccine (recombinant) in pregnant women.[1,3,4] Data on chikungunya vaccine (recombinant) administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.[1]

In a developmental toxicity study in female rabbits, administration of a single human dose of chikungunya vaccine (recombinant) on 5 occasions (i.e., twice prior to mating, twice during gestation, and once during lactation) reduced postnatal survival of kits, but no other postnatal adverse effects were observed.[1] There were no adverse effects on female fertility; and there was no evidence of fetal harm due to the vaccine.[1]

In a developmental toxicity study in female rats, administration of a single human dose of chikungunya vaccine (recombinant) on 5 occasions (i.e., twice prior to mating, twice during gestation, and once during lactation) had no adverse effects on postnatal survival or other postnatal development parameters.[1,] There were no adverse effects on female fertility.[1,]

Vertical transmission of wild-type chikungunya virus (CHIKV) to neonates from pregnant women with viremia at delivery is common and can cause severe, potentially fatal CHIKV disease in neonates, with neurologic (e.g., encephalopathy, intracranial hemorrhage) and myocardial manifestations.[1,]

Lactation.

Human data are not available to assess the impact of chikungunya vaccine (recombinant) on milk production, its presence in breast milk, or its effects on the breastfed child.[1,3,] The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for chikungunya vaccine (recombinant) and any potential adverse effects on the breastfed child from the vaccine or from the underlying maternal condition.[1,]

Pediatric Use.

Safety and effectiveness of chikungunya vaccine (recombinant) in individuals 12 through 17 years of age are based on data from this age group and data from adults.[1,3,] Safety and effectiveness of chikungunya vaccine (recombinant) in individuals younger than 12 years of age have not been established.[1,]

Geriatric Use.

In one of the principal efficacy studies, the 206 individuals who received chikungunya vaccine (recombinant) were 65 years of age and older; among these, 47 individuals (22.8%) were 75 years of age and older.[1,] The incidence of solicited adverse reactions in individuals 65 years of age and older was generally lower than that observed in individuals less than 65 years of age.[1,] The seroresponse rate in individuals 65 years of age and older was lower than that observed in individuals less than 65 years of age.[1,]

▪ Common Adverse Effects

The most commonly reported solicited adverse reactions (>10%) in individuals 12 through 64 years of age were injection site pain (23.7%), fatigue (19.9%), headache (18.0%), and myalgia (17.6%).[1,]

The most commonly reported solicited adverse reactions (>5%) in individuals 65 years of age and older were injection site pain (5.4%), myalgia (6.3%), and fatigue (6.3%).[1,]

Drug Interactions

No formal drug interaction studies have been performed to date with chikungunya vaccine (recombinant).[1,]

Description

Chikungunya vaccine (recombinant) is a recombinant vaccine containing purified virus-like particles (VLPs) consisting of chikungunya virus (CHIKV) capsid protein (C) and envelope proteins E1 and E2, derived from CHIKV Senegal strain 37997.[1,5,] The exact mechanism of protection of the vaccine has not been determined.[1,3,5,] Chikungunya vaccine (recombinant) elicits CHIKV-specific immune responses.[1,3,5,]

The time to effectiveness of chikungunya vaccine (recombinant) (defined as seroresponse and serum neutralizing antibody geometric mean titer) was achieved at Day 22.[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).

Advise vaccine recipients about the potential benefits and risks associated with vaccination with chikungunya vaccine (recombinant).[1,]

Advise vaccine recipients that vaccination with chikungunya vaccine (recombinant) may not protect all vaccine recipients and that personal precautions should be taken to reduce exposure to mosquito bites (e.g., adequate clothing, use of repellents, mosquito nets).[1,]

Instruct the vaccine recipient to report any adverse reactions to their health care provider, the vaccine manufacturer at 1-833-365-9596 (or online at https://bavarian-nordic.com (https://bavarian-nordic.com)), or through the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 (or online at https://vaers.hhs.gov/ (https://vaers.hhs.gov/)).[1,]

Advise patients to inform their clinician of existing or contemplated concomitant therapy, including prescription and OTC drugs and dietary or herbal supplements, as well as any concomitant illnesses.[1,]

Advise patients to inform their clinician if they are or plan to become pregnant or plan to breast-feed.[1,] Encourage women exposed to chikungunya vaccine (recombinant) around the time of conception or during pregnancy to enroll in the pregnancy registry by calling 1-888-230-2491or by visiting https://bnpregnancyregistry.com (https://bnpregnancyregistry.com) .[1,]

Inform patients of other important precautionary information.[1,]

Additional Information

The American Society of Health-System Pharmacists, Inc. represents that the information provided in the accompanying monograph was formulated with a reasonable standard of care, and in conformity with professional standards in the field. Readers are advised that decisions regarding use of drugs are complex medical decisions requiring the independent, informed decision of an appropriate health care professional, and that the information contained in the monograph is provided for informational purposes only. The manufacturer's labeling should be consulted for more detailed information. The American Society of Health-System Pharmacists, Inc. does not endorse or recommend the use of any drug. The information contained in the monograph is not a substitute for medical care.

Preparations

Chikungunya vaccine (recombinant) is obtained through designated distributors.[2,] Contact manufacturer or consult the chikungunya vaccine (recombinant) website (https://bnvaccines.com/contact-us (https://bnvaccines.com/contact-us)) for specific availability information.[2,]

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

Chikungunya Vaccine (Recombinant) (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Chikungunya+Vaccine+%28Recombinant%29&collapse=1)

Parenteral

Injectable suspension, for IM use

Each 0.8 mL contains approximately 10 ug chikungunya virus senegal strain 37997 capsid protein, 15 ug chikungunya virus senegal strain 37997 envelope protein E1, and 15 ug chikungunya virus senegal strain 37997 envelope protein E2

Vimkunya®, Bavarian Nordic A/S (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=LabelerName&ApptName=Bavarian+Nordic+A%2FS&collapse=1)

Related Resources

AHFS Patient Medication Information (https://vsearch.nlm.nih.gov/vivisimo/cgi-bin/query-meta?v:project=medlineplus&query=Chikungunya%20Vaccine,%20Recombinant) 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:%%22Chikungunya%20Vaccine,%20Recombinant%%22) (Chemical Carcinogenesis Research Information System)
ChemID*plus* (https://chem.nlm.nih.gov/chemidplus/name/Chikungunya%20Vaccine,%20Recombinant)
Biochemical Data Summary (http://www.drugbank.ca/unearth/q?utf8=%%E2%%9C%%93&query=Chikungunya%20Vaccine,%20Recombinant&searcher=drugs&approved=1&vet_approved=1&nutraceutical=1&illicit=1&withdr (US and Canada)
Clinical Trials (https://www.clinicaltrials.gov/ct/search?submit=Search&term=Chikungunya%20Vaccine,%20Recombinant)
DailyMed (https://dailymed.nlm.nih.gov/dailymed/search.cfm?query=Chikungunya%20Vaccine,%20Recombinant) (drug labels)
DART (https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+dart:%%22Chikungunya%20Vaccine,%20Recombinant%%22) (Developmental and Reproductive Toxicology Database)
Drugs@FDA (https://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchType=BasicSearch&SearchTerm=Chikungunya%20Vaccine,%20Recombinant) (approval information)
European Medicines Agency (https://www.ema.europa.eu/en/search/search?search_api_views_fulltext=Chikungunya%20Vaccine,%20Recombinant)
FDA National Drug Code Directory (https://www.accessdata.fda.gov/scripts/cder/ndc/default.cfm?sugg=NonProprietaryName&ApptName=Chikungunya%20Vaccine,%20Recombinant&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:%%22Chikungunya%20Vaccine,%20Recombinant%%22) (Hazardous Substances Data Bank)
Inxight Drugs (https://drugs.ncats.io/substances?q=%%22Chikungunya%20Vaccine,%20Recombinant%%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+%%22Chikungunya%20Vaccine,%20Recombinant%%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=Chikungunya%20Vaccine,%20Recombinant) (therapeutic equivalence)
PharmGKB (https://www.pharmgkb.org/search?connections&gaSearch=Chikungunya%20Vaccine,%20Recombinant&query=Chikungunya%20Vaccine,%20Recombinant&type=chemical) (Pharmacogenomic data from PharmGKB)
Pillbox (*beta*) (https://pillbox.nlm.nih.gov/pillimage/search_results.php?submit=Search&splid=&getingredient=Chikungunya%20Vaccine,%20Recombinant) (drug identification and images)
PubMed (https://www.ncbi.nlm.nih.gov/pubmed?DB=pubmed&term=Chikungunya%20Vaccine,%20Recombinant%%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:%%22Chikungunya%20Vaccine,%20Recombinant%%22) (Toxicology Literature Online)

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

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