

At the time of initial posting on June 25, 2021, individuals using assistive technology may not be able to fully access the information contained in this document. A fully accessible version of the document is in preparation and will be posted as soon as it is ready. We regret any inconvenience that this may cause our readers. For assistance, please send an e-mail to ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

PEPA IN MELELE KO REMOOL ÑAN RO REJ LOLOORJAKE Ājmuur IM AENÖMMAN

IDIÑIN JERBAL ÑAN KÖMELIM WĀIN BÔBRAE KIJ IN NAÑINMEJ IN KÔRONA 2019 (COVID-19) EKKĀ AN PÄD IPPÄN RO 12 AER IIÖ IM RÜTTOŁOK

Emōj an kar iwōj wāin bōbrae kijin nañinmej in Kōrona 2019 (COVID-19) ekar kōmman jān SARS-CoV-2. Pepa in me ejimwe im jejjet melele ko ie ej ñan jipañ iok melele ko kōn nana im emm̄an ko an wāin bōbrae kijin nañinmej in ekajoor ḥa etan COVID-19.

Wāin bōbrae kijin nañinmej in COVID-19 ej juon wā eo ñan bōbrae iok jān am bōke COVID-19. Etan jikin eo ej etale mōñā im uno ko rekajjor ilo Amedka (FDA) ekkar koweppe wāin ñan bōbrae COVID-19.

Riiti pepa in emool melele ko ie ikijien wāween kōjerbal wāin bōbrae kijin nañinmej in COVID-19. Kōnono ippān ro rej bōk eddoin wā kein elaññe ewōr am kajjitōk. Am pepeñe koknaan bōke wāin bōbrae kijin nañinmej in COVID-19 in.

Wāin bōbrae kijin nañinmej in COVID-19 in ekar weppān ippān rej lolorjake ke tarrin 2 kōttan am wā ilo ālkin wiik kein 3, ñan an jipañ majel ko.

Wāin bōbrae kijin nañinmej in COVID-19 emaroñ jab kōmour aolep armej.

Pepa in emool melele ko ie ekar dedejok aer etale im etōnwadik. Ñan am lukkun bōk melele ko rōkāäl ḥok, jouj im lale wāpjait in www.cvdvaccine.com.

TA KO KWOJ AIKUJ IN JEŁĀ MOKTA JĀN AM BÖK WĀIN?

TA IN COVID-19?

COVID-19 ekar wałok jān kijin Kōrona ḥa etan SARS-CoVID-2. Nañinmej jabin Kōrona ejjañin kar wałok kar mokta ḥok. Komaroñ bōk kijin nañinmej in COVID-19 jān am epaake ak uñur juon armej eo ewōr ippān kij in. Nañinmej in ej nañinmej in ār ak orłok ak pen ad menono im emaroñ kakkure ak jelöt jet iaan mōttan ko ilo ialan menono ak kōto eo. Armej ro rebōk nañinmej in COVID-19 ekar wōr kakkōlkōl ko ippāer rōkar pād ilo riboot ke ewōr air nañinmej. Kakkōlkōl kein remaroñ wałok ak jede 2 ḥok ñan 14 raan ālikin an pād kij in. Kakkōlkōl kein emaroñ wōr: Pipa; Pokpok; Jabjabin menono; kaijinōk; Metak; majel ak ānbwinin; Metak bar; Ekaäl an jako am kōnemnem ak kāätet; Mōrā bōro; Boñ boti ak uwūr; Małōñlōñ ak emm̄oj; Ilǫk loje.

TA IN WĀIN BÔBRAE KIJIN Nañinmej in COVID-19?

Wāin ej juon wā eo ekar jab alikar kōjerbale ñan bōbrae COVID-19.

Ejjelok alikar jān FDA ñan kōjerbal wāin ñan bōbrae nañinmej in COVID-19.

FDA EO ekar kōmalim ilo jidimkōj wāin bōbrae kijin nañinmej in COVID-19 ippān ro 12 aer iiō im rüttołok ium̄win kappe eo an (EUA).

Ñan melele ko rellap lók ikijien EUA, lale “**Ta in Emergency Use Authorizatin (EUA)**?” Jāakjen eo jemłokin Pepa in.

TA EO KWOJ BA ÑAN RUWĀ RO MOKTA JĀN AM BŌK WĀIN COVID-19 EO?

Ba ña ruwā ro ikijien nañinmej ko am, ekoba eñaññe kwoj:

- Ewōr ke men eñ enana ñan am iddak ak mōñā em emaroñ kōnañinmej iok
- E kar wor ippam myocarditis (ebbōj ilo majeł an menono eo) ak pericarditis (ebbōj jikin tu-likin menono eo)
- ewōr ke am pipa
- Kwoj tqorłok ke kōn bōtōktōk
- Ewōr ke am nañinmej in ār ak ewōr ke uno en ej kakkure iok
- Kwoj neji ke ak ewōr ke am lōmñak in neje
- Kwoj kanninnin ke
- Kokar ke bar wāin COVID-19
- Kwar lōtłok ke kwar wā mokta

WŌN EO EJ AIKUJ IN BŌK WĀIN BŌBRAE KIJIN NAÑINMEJ IN COVID-19?

FDA ekar kōmalimi köjerbale ilo juon tore eo ejidimkij ñan ro 12 aer iiō im rūttolok.

WŌN EO EJJAB AIKUJ IN BŌK WĀIN BŌBRAE KIJIN NAÑINMEJ IN COVID-19?

Kwoj jab aikuj in bōk wāin bōbrae kijin nañinmej in COVID-19 elaññe kwoj

- Kokar bōke em kadōke ālkin am wā
- Kokar bōke em kadōke ekkar itok jān kāre ko an

TA KĀĀREIN WĀIN AN KIJIN BŌBRAE NAÑINMEJ IN COVID-19?

Wāin in bōbrae kijin nañinmej in COVID-19 koba laajrakin kāre ko an:

RNA, lipids ((4-hydroxybutyl)azanediyil)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2-(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

EWI WĀWEEN LEŁOK WĀIN BŌBRAE KIJIN NAÑINMEJ IN COVID-19?

Wāin bōbrae kijin nañinmej in COVID-19 enaaj iwōj ñan iok āinwōt ilo aer dibōjłok ak wāikłok majel eo.

Wāin bōbrae kijin nañinmej in COVID-19 enaaj iwōj 2 alen ilo kajjojo 3 wiik ko.

Eñaññe kobok juon alen wāin bōbrae kijin nañinmej in COVID-9, kwoj aikujin bar bōke ruo ale ilo ejjab tore eo wōt ālkin 3 wiik ñan kadedeikłok bōk wāin.

WĀIN BŌBRAE KIJIN NAÑINMEJ IN COVID-19 EKAR KE JERBAL MOKTA ŁOK?

Wāin bōbrae kijin nañinmej in COVID-19 ekar jab ellā āinwōt juon uno. Ilo jikin kakōlkōl ko, iturin lók 23,000 kajjojo armej ro 12 aer iiō im rūttolok rekar bōk wōt juon alen aer kar wā.

TA TOKJEN KO AN WĀIN BŌBRAE IN?

Ilo an wōnmaanlōk wōt jikin jerbal in etale nañinmej ko, uno in ak wāin ej kwałok im kalikar ke ej ñan bōbrae COVID-19 ilo ad ɻoor wōt wāweenin 2 alen bōke ilo 3 mōttan in wiik ko. Tōre ko ñan bōbrae nañinmej in COVID-19 kiō ejjab alikar.

TA NANA KO AN WĀIN?

Ewōr jet iien ej make jejnijnij iien an wałok nañinmej in im kōm̄man bwe wāin en maroñ pen an jerbal. Nañinmej in emaroñ bar wałok ālikin jejjo minit ko ak lokin juon awa ālikin bōk wāin. Kōn men in, ruwā eo am e maroñ kajjitōk ippam bwe kwōn pād wōt ijo kwar wā ie jidik bwe ren lale eok. Kakkōlle ko:

- Epen am menono
- Eppōj turin mejān im buruōn
- Kajjinōk
- Ekilbūrōrō ānbwinūn
- Addōbboulul im mōjno

Ippān jet armej me raar bōk wāin bōbrae COVID-19 eo an Pfizer-BioNTech, ear wor myocarditis (ebbōj ilo majeļ an menono eo) im pericarditis (ebbōj jikin tu-likin menono eo). Ippān enañin aolepen armej rein, kakōlle ko an nañinmej kein raar jino in wałok iumwin jet raan ālikin aer kar bōk wā eo kein ka ruo, wāin bōbrae COVID-19 eo an Pfizer-BioNTech. Ejeja an wałok ippān armej. Elaññe kakōlle kein ippam, kwōn taktō ilo iien eo e mōkajtata ālikin am bōk wāin bōbrae COVID-19 eo an Pfizer-BioNTech:

- Metak ob
- Epen am menono
- Eñjake bwe e iim ak kajoor an bam menono ne am

Ijoko rejelelōti ekar riboot ikijjen wāin:

- Jorrāān ko āinwōt ñe armej rej kadek kake wūno
- Mōnōjnōj, kilbūrōrō, ak ebbōj turin mejōm
- Myocarditis (ebbōj ilo majeļ an menono eo)
- Pericarditis (ebbōj jikin tu-likin menono eo)
- emetak ijo rekar wāiki
- emmōkṁōk
- Metak bar
- Metak majeļ
- Nimoonia
- Metak ekkeitaak ko
- Pipa
- ebbōj ijo rekar wāiki
- ebūrōrō ijo rekar wāiki
- Bon bøoti
- Enana an mour
- Ebbōbōj ānbwinnin
- Pidodo loje
- Emmōj

- Metak pā

Men kein aolep rejjab pidodo ilo aer jelōt nañinmej in COVID-19. Wāin rej ekkatak wōt kake ilo jikin kakkōlkōl ko.

A IMAROÑ KÖMMANE IKIJJIEN IJOKO EWÔR NAÑINMEJ IN IE?

Ñe ewōr am̄ imminene ikijjién nañinmej in, kūrlök 9-1-1, ak jibadōklok jikin taktō eo epaake iok.

Kūrlök ribōk eddo ro ak jikin ājmuur eo elāññe ewōr ijeñ ejelōte ippam em ej kōnanaik am̄ mour im jab ko.

Ribooti ijoko ewōr nañinmej ie ñan **FDA/CDC Vaccine Adverse Reporting Systems (VAERS)**. Nōmba eo an toll-free in ej 1-800-822-7967 ak riboote ilo önüain <https://vaers.hhs.gov/reportevent.html>. Jouj dood ‘Pfizer-BioNTech COVID-19 Vaccine EUA’ ilo Jain eo jinojn ilo bōk #18 in pepain riboot eo.

Ñan waanjoñak, komaroñ riboote ijoko ewōr nañinmej in ie ñan Pfizer Inc. ilo nōmba kein an ilal.

Weep jait	Pāák Nōmba	Talboon
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

Bōlen kwō maroñ pād ilo būrookraam eo etan in v-safe. V-safe ej juon men kāäl ilo smartphone ko im ej kajerbal text message im survey (kajjitōk im uwaak) ilo online bwe en lale elāññe ewor jorrāān ippān armej me emōj aer wā kōn COVID-19. V-safe ej kajjitōk ippān armej bwe en emmān an CDC eo lale joñan an emmān im safe wā ko kōn COVID-19. Kab V-safe ej kakememej armej bwe ren bōk wā kein ka ruo elāññe rej aikuji, im armej jān CDC renaaj call elāññe juon armej ej ba bwe elāp an nañinmej ālikin an bōk wā in bōbrae COVID-19. Ñan melele ko relaplok kōn wāween pād ilo būrookraam in, etal ñan: www.cdc.gov/vsafe.

AK ELĀÑÑE IJJAB LÖMNAKIN BOK WĀIN?

Kālōt ne ej am̄ ñan am bōke akō jab bōke wāin. Kwoj ke lomnak in jab bōke wāin, eban ukōte iok.

EWÔR KE JET WĀWEEN KO RALIKAR ÑAN BÖBRAE COVID-19 IJJELÖKIN WĀIN BÖBRAE KIJIN NAÑINMEJ IN COVID-19?

Kiō, ejjełok jet uno ko me emōj kar kapeni im ralikar ñan kabōjrak COVID-19. E maroñ wor bar jet wā in bōbrae COVID-19 ekkar ñan pepe in Kamālim in Kajerbale ilo iien Emergency in (EUA).

IMAROÑ KE BOK WĀIN BÔBRAE KIJIN NAÑINMEJ IN COVID-19 IPPĀN BAR UNO AK WĀ KO JET?

Ejjañin wōr melele ko ikijjen ad maroñ kakkobaiki wāin ippān bar jet uno ak wā koi lo ad kōjerbale.

TA EO ÑE INAAJ BÔRORO AK KANNIN?

Ñe kwôbôroro ak kwoj kanninin, Kônono ippān ro rej eddoin ájmuur kōn wâween ko kwoj lõmñaki im rekkar.

WĀIN BÔBRAE KIJIN NAÑINMEJ IN COVID-19 EN EK LETOK ÑAN IÔ NAÑINMEJ IN COVID-19?

Wāin bôbrae kijin nañinmej in covid-19 ejjab pâd SARS-CoV-2 ie im eban lewaj am nañinmej in COVID-19.

KÔJPAROK KAATIN WĀ EO AM

Ñe kwobôke wā eo jinoin tata, kwonaj bok juon am kaatin wā ñan kalikar ñan kwe iien rool eo am. Keememej in bar bôktok kaat eo am ippam tok elaññe kwonaaj bar rool tok tokâlik.

KOKKOBABAIN MELELE

Ñe ewôr am kajjitôk, lale webjaitin im deloñe ak kurtok talboon nombain epâd ijin ilaļ.

Ñan am bok melim iñan deloñe Fact Sheet eo, jouj im jikâane QR nombia eo itulaļ. Deloñe FDA eo ilo

Weepjait	Talboon
www.cvdvaccine.com 	1-877-829-2619 (1-877-VAX-CO19)

EWI WÂWEEN BWE IN MAROÑ BAR EKKATAK ELAPLOK?

- Kajjitôk ippān ro tellokier.
- Deloñe CDC ilo weepjaitin <https://www.cdc.gov/coronavirus/2019-ncov/index.html>.
- Deloñe FDA eo ilo <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.
- Kûrlök kien eo edik ak jikin ajmuur eo elap

IA EO REKOOT IN WĀ KO RENAAJ PĀD IE?

ri-Lolorjake wā kein renaaj lewaj ñan melele ikijjen wā kein ñan jikin eo kwoj pād ie/Ijo emōj an kien kōmaroñe bwe en wā kein(IIS). Menin enaj kalikare ke emōj am bōke wāin elāññe kwonaaj bar rool ñan am bōke kein karuo. Ñan melele ko rel̄lap lōk ikijjen jikin in ba kake ijin (IISs) Deļoňe weepjait in an:

[https://www.cdc.gov/vaccines/programs/iis/about.html.](https://www.cdc.gov/vaccines/programs/iis/about.html)

RENAAJ KE BA BWE IN KÖLLĀ KŌN AŌ BŌK WĀ IN BŌBRAE COVID-19?

Jaab. Ilo tōre in, jikin taktō eo e jab maroñ charge eok kōn juon wā in bōbrae, im re jab maroñ charge eok kōn oñean taktō ak bar jet fee elāññe men eo wōt kwōj kōmmane ej bōk wā in bōbrae COVID-19. Bōtab, ro rej lelōk wā in bōbrae re maroñ kajjitōk bwe juon būrookraam ak plan me e kijoñ in kōllā oñean wā in bōbrae COVID-19 en kōllā (insurance an armej make, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 Uninsured būrookraam ñan ro im ejjelelōk aer insurance).

ELAÑÑE IJ LÖMNAK BWE JET ARMEJ REJ RIAB IN BŌK JĀĀN KO ME REN KAR JAB BŌKE, IN KWALÖKE ÑAN WÖN?

Elaññe juon armej ej lōmñak bwe ewor ro im rej kokkure kien ko an CDC Wā in Bōbrae COVID-19 Būrookraam, ren kwalöki ñan Opij eo an Inspector General, U.S. Department of Health and Human Services (Tibaatmen in Ājmour), ilo 1-800-HHS-TIPS ak <https://TIPS.HHS.GOV>.

TA IN CICP BŪROOKRAAMIN?(BŪROOKRAAM IN JIPAÑ ARMEJ RO IKIJJIEN KÖLLĀ ONEEN TAKTŌ IM KO ĀIERLÖK WÖT KO REJELÖTIER)?

Būrookraam in (CICP) ej pād iumin kien an Amedka em ej jipañ ñan kōllā oñeen takō im bar oñeen ko jet ñan kōllā uno ko im rejipña nañinmej in ekoba oñeen wāin. Ilo jejjetin, juon abñōñō ej aikuj in etal ñan CICP eo juon(1) iio jān tore eo ekar bōke wāin. Ñan am katak elap lōk kōn būrookraam in, deļoňe weepjait in www.hrsa.gov/cicp/ ak kūrlōk 1-855-266-2427.

TA IN JIKIN ÑAN BŌK MELIM ILO IDIÑ (EUA)?

Amedka FDA eo ekar kōmmane wāin bōbrae kijin nañinmej in COVID-19 im ewōr kiō il ra eo an EUA. Jekretari eo an jikin ĀJMUUR koba ra ej lolorjake jokkin mour an armej erro rej eddoin EUA.

Wāin COVID-19 in ejjab etal em jako ak pōjrak āinwōt juon jerbal in etal an FDA-ekar koweppan ak kōkmanman jerbal in. FDA emaroñ lelōk jipañ ñan juon EUA elāññe ekar wōr menin aikuj ko rel̄lap rej aikuj in kar bōk jkier. Barāinwōt, karōk eo an FDA ej pedped wōt ioon joñan menin kamool ko reped im rej kalikar ke tōprak in jerbal in epolel. Aolepen jibabbadin köttōbar kein rej aikuj in kar alikar bwe ren tōpar aorōkin jerbal in kōmour ri-nañimej ilo tore eo ewōr nañinmej in COVID-19.

EUA eo kōn wāin bōbrae ikijjen kijin nañinmej in COVID-19 ej jejjet kitien ilo tore ne ewōr nañinmej in COVID-19 EUA eo wōt enaaj kalikar im kōmlet kōn ñaat eo wā kein renaaj jino aer jerbal im boōjrak aer jerbal (Ālikin wōt an alikar ke wā kein rejjab bar maroñ in jerbal).



Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH

Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-4.2a
Kar kajjimwe ilo: 25 Juun 2021



Jikeene pepa in elap im mool melele ko je ekar iwjöi ñan
iabdewöt armei ro ewör aer nañinmei in ñan an päd
rekootin taktö ko am ilo jikin taktö eo ilo kamputör ko je.

Tore eo an nömba in 05/2021

FDA ekar kōmman ukok kein āinwōt jerbal in jipaň ḥok juon doulul ak armej ro rej aikuj jipaň ikijjen ukok ilo kajin ko aer. Kōmij tōmak im kajtdikdik ke ukok kein renaaj jipaň iok melele. Ilo an kar jikin jerbal in kōmmane ukok kein rekkar kanooj in pen im kōmmetak ilo am ukot ñan kajin pälle, kōmij kile ke ukok kein rekar jab kanooj in polel im alikar ak jab dedeļok ilo ukokin ñan kajin pälle eo. Lukkun kajin eo kōjerbali ilo pepa kein ej ilo kajin Pälle.