IMPAPURO Z'INKURU ZEMEWE KU BARONKA URUCANCO HAMWE N'ABABITAHO IBIJANYE NA COMIRNATY (URUCANCO RWA COVID-19, mRNA) HAMWE N'URUCANCO RWA PFIZER-BIONTECH RWA COVID-19 RUKINGIRA UMUGERA WA CORONAVIRUS INDWARA YA 2019 (COVID-19)

Uriko uhabwa urucanco yaba urwa COMIRNATY (urucanco rwa COVID-19, mRNA) canke urucanco Pfizer-BioNTech rwa COVID-19 rukingira indwara ya Coronavirus 2019 (COVID-19) iterwa na SARS-CoV-2.

Aya makuru y'urucanco ari k'urupapuro rwizewe ku baruronka hamwe n'ababitaho rurimwo urupapuro rwizewe k'urucanco rwemewe rwa COVID-19 arirwo Pfizer-BioNTech hamwe kandi n'amakuru ajanye n'urucanco FDA-licensed, COMIRNATY (Urucanco rwa COVID-19, mRNA).

Urucanco FDA-approved COMIRNATY (Urucanco rwa COVID-19, mRNA) hamwe n'urucanco rwa COVID-19 rwitwa BioNTech bihagarariwe n'uruhusha rwo kurukoresha vyihuse (EUA) zikoze kumwe kandi zishobora gukoreshwa kimwe m'urukurikirane rwo gutanga urucanco COVID-19.[1]

Urucanco COMIRNATY (Urucanco rwa COVID-19, mRNA) ni urucanco rwa COVID-19 rwa FDA-approved rwakozwe na Pfizer kubwa BioNTech.

- **Zemewe nka doze 2 m'urukurikirane rwo gukingira COVID-19 abantu b'imyaka 16 n'abayirenza.**
- **Biremewe kandi na EUA ko rutangwa kugira:**
  - **rukingire COVID-19 abantu mumyaka 12 gushika 15, kandi**
  - **hatangwe doze ya gatatu ku bantu b'imyaka 12 hamwe n'abayirenza barutewe boba bafise ingorane z'abasoda b'umubiri.**

Urucanco Pfizer-BioNTech rwa COVID-19 rwararonse EUA ruvuye kuri FDA kugira:

- **rukingire COVID-19 abantu b'imyaka 12 hamwe n'abayirenza, kandi**
- **hatangwe doze ya gatatu ku bantu b'imyaka 12 hamwe n'abayirenza barutewe boba bafise ingorane z'abasoda b'umubiri.**

Uru rupapuro ruriko amakuru yizewe y' urucanco hariko amakuru agufasha gutahura ingaruka hamwe n'akamaro ka COMIRNATY (Urucanco rwa COVID-19 Vaccine, mRNA) hamwe na Pfizer-BioNTech urucanco rwa COVID-19, urwo ushobora kuronka kubera hariho ikiza muri iki gihe ca COVID-19. Vugana n'uwujejwe kuguha urucanco nimba ufise ibibazo.

Urucanco COMIRNATY (Urucanco rwa COVID-19, mRNA) hamwe na Pfizer-BioNTech urucanco rwa COVID-19 ziterwa m'urukurikirane rwa doze 2, indwi 3 ziheze, mu mitsi.

[1] Urucanco rukwije ibisabwa rukoze cokimwe n'urucanco EUA-authorized vaccine kandi zishobora gukoreshwa kimwe canke m'urukurikirane rwo gucandaga hatarinze kwerekana ubudahangarwa na bumwe canke ibijanye n'ubukomezi. Incanco zifise itandukaniro rito bituma zitagira ingaruka hamwe n'ubukomezi.

Bihagarikiwe na EUA ku bantu boba bafise ingorane z'abasoda b'umubiri, doze ya gatatu ishobora guterwa nimiburiburi indwi 4 inyuma ya doze ya kabiri.

Urucanco COMIRNATY (Urucanco rwa COVID-19, mRNA) hamwe n'urucanco Pfizer-BioNTech rwa COVID-19 ntizishobora gukingira abantu bose.

Ururupapuro rw'ukuri rushobora kuba rwashizwe kugihe. Ukeneye urukaratasi rutangirwako insiguro rwa vuba, usabwe kwugurura www.cvdvaccine.com.

ICO UKENEYE KUMENYA IMBERE YOKURONKA URU RUCANCO

COVID-19 NI IKI?

Indwara ya COVID-19 iterwa n'umugera coronavirus witwa SARS-COV-2. Urashobora kwandukizwa COVID-19 bivuye ku kwegerana n'uwundi muntu yanduye uwo mugera. Ahanini ni indwara ijanye no guhema ishobora gufata ibindi bihimba. Abantu bafise COVID-19 bafise ibimenyetso vyinshi bidasa bimaze kumenyekana, bihera kubimenyesto bibayabaye gushika ku bimenyetso bikaze bishikana no ku rupfu. Ibimenyetso bishobora kwibonekeza ku munsi wa 2 gushika kuwa 14 kuva aho ushobora kuba waregeranye n'umugera. Mu bimenyetso hashobora kuba harimwo: umucanwa canke kujugumira; inkorora; guhema udashikana; uburuhe; kubabara mu mumitsi canke mu mubiri; kumeneka umutwe; kudasoserwa canke kutamoterwa; kubabara mu muhogo; amazuru afunze canke ufise ibicurane; iseseme canke kudahwa; gucibwamwo.

COMIRNATY NI IKI (URUCANCO RWA COVID-19, mRNA) KANDI NI GUTE RUFITANIYE ISANO N'URUCANCO PFIZER-BIONTECH RWA COVID-19?

Urucanco COMIRNATY (Urucanco rwa COVID-19, mRNA) hamwe n'urucanco rwa COVID-19 rwitwa BioNTech zikoze kumwe kandi zishobora gukoreshwa kimwe canke m'urukurikirane rwo gucandaga COVID-19.[2]

Kuyandi makuru kuri EUA, raba agace ka "**Ni iki Uruhusha Rwogukoresha Vyihutirwa (EUA)?**" mu mpera ry'uru rupapuro rw'ukuri.

[1]Urucanco rwemewe n'amategeko rukoze cokimwe n'urucanco EUA-authorized kandi zishobora gukoreshwa kimwe canke ikindi m'urukurikirane rwo gucandaga hatarinzwe kwerekana uburinzi na bumwe canke ibijanye n'ubukomezi. Incanco zifise itandukaniro rito bituma zitagira ingaruka hamwe n'ubukomezi.

NI IKI UKWIYE KUBWIRA UWUKURONSA URUCANCO IMBERE YUKO URONSWA URUCANCO?
Barira umutangabufasha muvy'ubuvuzi ujejwe gucandaga ibiraba indwara zose ufise, harimwo nimba:

- urahurirwa mu buryo ubwaribwo bwose
- ufise myocarditis (ubuvyimbe mu mitsi y'umutima) canke pericarditis (ubuvyimbe bwo hanze y'umutima)
- ufise ubushuhe
- Woba ufise indwara yo kuva amaraso canke uriko urafata imiti ituma amaraso adafatana
- sisitemu yo kwirinda mu mubiri wawe ifise ikibazo canke uri ku miti ifise ingaruka kuri sisitemu yo kwirinda y'umubiri wawe
- uribugenze canke uriko urategekanya kwibungenga
- uronsa
- warahawe urundi rucanco rwa COVID-19
- woba warigeze kuraba bivuye kuguterwa urushinge

NINDE ATEGEREZWA KURONKA URUCANCO?
FDA yaremeje COMIRNATY (urucanco rwa COVID-19, mRNA) kugira rukore kubantu abafise imyaka 16 hamwe n'abayirenza kandi bafise uruhusha rwo kuruterwa vyihuse ku bantu imyaka 12 gushika 15.

FDA yatanze uruhusha rwo gukoresha mu buryo bwihutirwa urucanco Pfizer-BioNTech COVID-19 rwo gukingira indwara abantu bafise imyaka 12 y'amavuka kuduga.

NINDE <u>ADA</u>TEGEREZWA KURONKA URUCANCO?
Ntutegerezwa kuronkaurucanco COMIRNATY (Urucanco rwa COVID-19, mRNA) hamwe n'urucanco Pfizer-BioNTech rwa COVID-19 nimba:

- waraziraniwe canke wahuriwe bikaze uhejeje guterwa doze ya mbere y'uru rucanco
- niwaba waraziraniwe bikaze n'ibintu bigize uru rucanco.

NI IBIKI BIGIZE COMIRNATY (URUCANCO RWA COVID-19, mRNA) HAMWE N'URUCANCO PFIZER-BIONTECH RWA COVID-19?
COMIRNATY (Urucanco rwa COVID-19, mRNA) hamwe n'urucanco Pfizer-BioNTech rwa COVID-19 harimwo ibi ibikurikira: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6-1diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3- phosphocholine, na cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, na sucrose.

NI GUTE URUCANCO RUTANGWA?
Urucanco COMIRNATY (Urucanco rwa COVID-19, mRNA) hamwe n'urucanco Pfizer-BioNTech rwa COVID-19 uzoruhabwa biciye mu rushinge ruterwa mu mumutsi.

Urukurikirane rwa doze 2 zitangwa inyuma y'indwi 3.

Ucandajwe iryambere, ukwiye guca uronswa doze ya kabiri y'uru rucanco inyuma y'indwi 3 kugira uheze urukurikirane rwo gucandarwa.

HOBA HARAKORESHEJWE URUCANCO COMIRNATY (URUCANCO RWA COVID-19, mRNA) HAMWE N'URUCANCO PFIZER-BIONTECH UBWA MBERE?
Muvyageragejwe kwa muganga, abantu bababa 23,000 bafise imyaka 12 kuduga bararonkejwe nimiburiburi doze 1 y'urucanco Pfizer-BioNTech rwa COVID-19. Ibiharuro muri uko kugerageza vyarashigikiye ugukoresha urucanco Pfizer-BioNTech hamwe no kwemeza urucanco COMIRNATY (urucanco rwa COVID-19, mRNA). Amamiriyoni y'abantu bararonse urucanco Pfizer-BioNTech rwa COVID-19 Vaccine bihagarikiwe na EUA kuva muri Kigarama 11, 2020.

NI UBWAHE BURUSHO BWA COMIRNATY (URUCANCO RWA COVID-19, mRNA) HAMWE N'URUCANCO PFIZER-BIONTECH RWA COVID-19?
Urucanco rwarerekanye ko rukinga COVID-19 hisunzwe doze 2 zitangwa inyuma y'indwi 3. Umwanya wo gukingirwa COVID-19 nturamenyekana muri kino guhe.

NI IZAHE NZITIZI Z'URUCANCO COMIRNATY (URUCANCO RWA COVID-19, mRNA) hamwe n'URUCANCO PFIZER-BIONTECH RWA COVID-19?
Hariho amahirwe make y'uko urucanco rutera kuziranirwa bikaze. Kuziranirwa bikaze mu bisanzwe bishika inyuma y'iminota mike gushika kw'isaha inyuma yo guhabwa doze y'urucanco. Kuri iyi mpanvu, uwukuronsa urucanco ashobora kugusaba ugume mu kibanza waronkeye urucanco kugira agukurikirane inyuma y'urucanco. Ibimenyetso vyo kuziranirwa canke guhurirwa bikaze bishobora kuba ari:

- Guhema bigoranye
- Kuvyimba mu maso canke mu muhogo
- Umutima uriko urakubita ningoga
- Guhurirwa ku mubiri wose
- Kuzungurirwa no kwunva ata ntenge ufise

Myocarditis (ubuvyimbe mu mitsi y'umutima) canke pericarditis (ubuvyimbe bwo hanze y'umutima) bwaribonekeje ku bantu bamwe baronse urucanco COMIRNATY (urucanco rwa COVID-19, mRNA) canke urucanco Pfizer-BioNTech rwa COVID-19. Muri abo bantu benshi, ibimenyetso bitangura mu minsi mike inyuma yo kuronka doze y'urucanco rugira kabiri. Amahirwe yo kubona ibi biba ni make cane. Utegerezwa kurondera ubufasha bw'ubuvuzi ubwo nyene nimba wumvise bimwe muri ibi bimenyetso inyuma yo kuronka urucanco:

- Kubabara mu gikiriza
- Kubura impwemu
- Kwiyumva uhema vyihuse, kujugumira, canke umutima utera cane

Hariho ingaruka z'imiti zimaze kumenyeshwa k'urucanco COMIRNATY (Urucanco rwa COVID-19, mRNA) canke harimwo n'urucanco rwa Pfizer-BioNTech COVID-19:

- gufurutira umubiri wose bimwe bikabije
- kudafurutira bikabije umubiri wose , kuribwa k'umubiri, gukweguka, canke gukweguka isura
- myocarditis (ubuvyimbe mu mitsi y'umutima)
- pericarditis (ubuvyimbe bwo hanze y'umutima)
- ububabare aho watewe urushinge
- ukuruha
- kumeneka umutwe
- kubabara mu mitsi

- kujugumira
- kubabara mu ngingo
- ubushuhe
- kuvyimba aho watewe urushinge
- gutukura aho watewe urushinge
- iseseme
- kwunva utamerewe neza
- kuvyimba kumpande yizosi (lymphadenopathy)
- gucibwamwo
- kudahwa
- kubabara ukuboko

Izi zirashobora kuba atari zo nkurikizi zonyene z'urucanco. Ingaruka zikaze kandi zititezwe zishobora gushika. Ingaruka z'urucanco ziracigwa kugeza n'ubu mu mageragezwa yo mu bitaro.

NO KORA IKI KU NGARUKA?
Igihe wunvise uziraniwe bikaze, hamagara 9-1-1, canke wikishire ku bitaro biri hafi yawe.

Hamagara uwakuronkeje urucanco canke umutangabufasha wawe nimba ufise inkurikizi z'imiti zikubabaje zitariko zirahera.

Tanga raporo y'ingaruka ziturutse ku rucanco kuri FDA/CDC Vaccine Adverse Event Reporting System (VAERS). Hamagara ku buntu kuri nimero ya VAERS 1-800-822-7967 canke uje ku muhora ngurukana bumenyi https://vaers.hhs.gov/reportevent.html. Usabwe gushiramwo " COMIRNATY (Urucanco rwa COVID-19, mRNA)" canke " Pfizer-BioNTech COVID-19 EUA", nk'uko bisabwa, mu gace kambere k'agasandugu #18 mu cete ca raporo.

Vyongeye, urashobora kwitura Pfizer.Inc.kubijanye n'inkurikizi z'imiti. Ushobora kubasanga hano munsi.

Urubuga	Nimero ya Fax	Nimero ya terefone
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

Ushobora kandi guhabwa amahitamwo yo kwiyandikisha muri v-safe. V-safe ni porogarama nsha y'ubushake yo kw'iterefone ikoresha ubuhinga bwa none mu kurungika ubutumwa bugufi n'igendereza mu gusuzuma abantu bamaze kuronswa urucanco kugira umenye inkurikizi z'imiti umuntu ashobora kugira inyuma yokuronswa urucanco rwa COVID-19. V-safe ibaza ibibazo bifasha CDC gucungera umutekano w'urucanco rwa COVID-19. V-safe yongera ikibutsa abakwiye kuronka doze ya kabiri mu gihe babikeneye kandi CDC ikanabahamagara kuri terefone mu gihe abovyerekeye bavuze ko bagize inkurikizi ziboneka ku magara yabo inyuma yo kuronswa urucanco rwa COVID-19. Kugira uronke ayandi makuru y'ukegene wiyandikisha, raba: www.cdc.gov/vsafe.

NI GUTE NIMBA MFASHE INGINGO YO KUTARONKA COMIRNATY (URUCANCO RWA COVID-19, mRNA) CANKE URUCANCO PFIZER-BIONTECH RWA COVID-19?
Bihagarikiwe na EUA, ni wewe uhitamwo guhabwa canke kudahabwa urucanco. Mu gihe uhisemwo kudahabwa urucanco, ntaco bizohindura k'uburyo warusanzwe uronka ubuvuzi.

HOBA HARIHO AYANDI MAHITAMWO MU KWINGIRA COVID-19 UKUYEMWO COMIRNATY (URUCANCO RWACOVID-19, mRNA) CANKE URUCANCO PFIZER-BIONTECH RWA COVID-19?
Izindi canco zikingira COVID-19 zishobora kuba zihari vyemewe n'uruhusha rwo gukoresha vyihutirwa.

NDASHOBORA KURONKA COMIRNATY (URUCANCO RWA COVID-19, mRNA) CANKE URUCANCO PFIZER-BIONTECH RWA COVID-19 KU MWANYA UMWE NK'IZINDI NCANCO?
Ibiharuro ntibirashikirizwa FDA kubijanye no guterwa COMIRNATY (Urucanco rwa COVID-19, mRNA) canke urucanco Pfizer-BioNTech rwa COVID-19 kumwanya umwe n'izindi ncanco. Nimba uriko wiyumvira guterwa COMIRNATY (urucanco rwa COVID-19, mRNA) canke urucanco Pfizer-BioNTech rwa COVID-19 hamwe n'izindi ncanco, vugana n'uwujejwe kukwitaho kwa muganga amahitamwo yawe.

NI GUTE NIMBA MFISE ABASODA BAKE MU MUBIRI?
Nimba ufise abasoda bake mu mubiri, ushobora kuronka doze ya gatatu y'urwo rucanco. Doze ya gatatu ishobora kudatuma udasubira kurwara COVID-19 ku bantu bafise abasoda bake mu mubiri, kandi ushobora kuguma wikingira umubiri kugira wirinde COVID-19. Kanatsinda, abantu bawe bo hafi bategerezwa kwicandagisha.

NI GUTE MU GIHE NAHO NOBA NIBUGENZE CANKE NONSA?
Nimba wibugenze canke uriko uronsa, yaga n'umutangabufasha wawe muvy'amagara amahitamwo ufise
umutangabufasha.

COMIRNATY (URUCANCO RWA COVID-19, mRNA) CANKE PFIZER-BIONTECH URUCANCO RWA COVID-19 RUNTERA COVID-19?
Oya. Urucanco ntirurimwo SARS-CoV-2 kandi ntirushobora kugutera COVID-19.

GUMANA IKARATA YAWE Y'URUCANCO
Igihe uronse doze ya mbere, uzoronka ikarata y'urucanco uzokwerekana igihe ugarutse guhabwa doze ya kabiri canke nimba ufise abasoda bake mu mubiri, doze yawe ya gatatu ya COMIRNATY (Urucanco rwa COVID-19, mRNA) canke urucanco Pfizer-BioNTech rwa COVID-19. Uzokwibuke kuza ufise ikarata yawe ugarutse.

AYANDI MAKURU
Nimba ufise ibibazo, raba ku rubuga ngurukanabumenyi canke uhamagare kuri nimero ya terefone yanditse aha munsi.

Mu gushikira urukaratasi rutangirwako insiguro ruheruka gusohoka, nkundira usikane QR code iri aha munsi.

Urubuga ngurukana bumenyi rusangi	Nimero ya terefone
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

NOMENYA AYANDI MAKURU GUTE?
- Baza uwukuronsa urucanco.
- Raba ku rubuga rwa CDC kuri https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Raba FDA kuri https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Akura mu gisata kijejwe amagara y'abanyagihugu ku rwego rwa reta canke hafi yawe.

AMAKURU YANJE YO GUCANDARWA AZOKWANDIKWA HE?
Uwakuronkeje urucancoo ashobora gushira amakuru yawe mu ntara/muri sisitemu y'amakuru yo gukingirwa (IIS) canke mu zindi sisitemu zibigenewe. Ibi bizotuma uronswa urucanco nk'urwo waronse mu gihe ugarutse kuronswa doze ya kabiri. Ku yandi makuru kuri IISs, raba ku rubuga rwa: https://www.cdc.gov/vaccines/programs/iis/about.html.

NSHOBORA GUTANGA AMAHERA YO KURONKA URUCANCO RWA COVID-19?
Oya. Muri uyu mwanya, uwutanga urucanco ntashobora kukubaza amahera kuri doze y'urucanco kandi ntan'ifaranga na rimwe uzotanga mukuronka urucanco rwa COVID-19. Yamara, abatanga incanco bashobora kurondera kwisurwa bivuye kuri porogarama canke indinganizo ikurihira amahera y'urucanco rwa COVID-19 (asiranse y'abikorera utwabo, Medicare, Medicaid, Health Resources & Services Administration [HRSA] COVID-19 porogarama ku bantu batanditse na hamwe).

NI HEHE NOTANGA RAPORO MU GIHE HABAYE UBUSUMA?
Abantu bategerezwa kuba maso hamwe hoba ubusuma bwa CDC kuri porogarama yo gucandaga COVID-19 ibikenewe bisabwe gushikirizwa kubiro vy'umugenduzi mukuru, muri reta zunze ubumwe. Igisata ca serivise z'amagara y'abantu kuri 1-800-HHS-TIPS or https://TIPS.HHS.GOV.

NI IKI POROGARAMA IRABA ISHUMBUSHO RY'ABABABAJWE? Porogarama iraba ishumbusho ry'Ababajwe (CICP) ni porogarama ya federasiyo ishobora gufasha kuriha kuvuzwa canke ibindi bijanye no kuvuzwa ku bantu bamwebamwe bashobora kuba barababajwe bikomeye n'imiti imwimwe canke urucanco, harimwo n'uru rucanco. Muri rusangi, ikirego gitegerezwa gushikira CICP mu kiringo c'umwaka umwe (1) kuva ku musi waronkejwe urucanco. Kugira

umenye amakuru atomoye araba iyi porogarama, kuri www.hrsa.gov/cicp/ canke uhamagare 1-855-266-2427.

URUHUSHA RWOGUKORESHA VYIHUTWIRWA (EUA) NI IKI?
Uruhusha rwo gukoresha vyihutirwa (EUA) ni uburyo bufasha ukuboneka kw'imiti, harimwo incanco, mubihe vyihutirwa vy'amagara y'abantu, nko muri iki gihe c'ikiza ca COVID-19. EUA ishigikiwe n'Umushikiranganji ajejwe amagara y'abantu na Seruvise zironswa abantu (HHS) mu civugo gisobonura yuko ibihe turimwo bishigikira uburenganzira bwo gukoreshwa vyihutirwa imiti n'ibindi muri iki kiza ca COVID-19.

FDA ishobora gusohora EUA iyo ibintu bimwebimwe vyatunganijwe, ivyo navyo bikaba bisigura yuko ata kintu, cizewe,cemewe, canke ikindi gihari gishoboka. Vyongeye, ingingo FDA ifata ihagaze ku bintu vyose vy'ubushakashatsi bimaze kuboneka vyerekana yuko icasohotse gishobora kuba gikora mu gukungira COVID-19 muri iki kiza ca COVID-19 kandi inyugu zizwi n'inyungu zindi zishobora kuhabonekera ziruta ivyago bizwi n'ibishobora kuhabonekera. Ibi vyose bitegerezwa gusuzumwa kugIra vyemerwe yuko bikoreshwa mukuvura abarwayi muriki kiza ca COVID-19.

Iyi EUA k'urucanco Pfizer-BioNTech rwa COVID-19 hamwe na COMIRNATY izohera igihe umunyamabanga wa HHS azovuga ibijanye no gusigura ko EUA itakibaho canke igihe hazoba hari impinduka mukwemeza imiti nk'uko EUA itazoba igikenewe.

Pfizer
Yakozwe na
Pfizer Inc., New York, NY 10017

BIONTECH
Yakozwe kubera
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-7.2

Vyasubiwemwo: 23 Myandagaro 2021

Sikana kugira ufate yuko ururupapuro rwukuri rwahawe abaronswa urucanco kugira baronke amakuru ngurukanabumenyi/canke sisitemu iraba gukingirwa.

Itariki y'uturongo twa kode: 08/2021