Package leaflet: Information for the user

Comirnaty 3 micrograms/dose concentrate for dispersion for injection
Infants and children 6 months to 4 years
COVID-19 mRNA Vaccine (nucleoside modified)
tozinameran

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects your child may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Comirnaty is and what it is used for
2. What you need to know before your child receives Comirnaty
3. How Comirnaty is given
4. Possible side effects
5. How to store Comirnaty
6. Contents of the pack and other information

1. What Comirnaty is and what it is used for

Comirnaty is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty 3 micrograms/dose concentrate for dispersion for injection is given to infants and children from 6 months to 4 years of age.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty does not contain the virus to produce immunity, it cannot give your child COVID-19.

2. What you need to know before your child receives Comirnaty

Comirnaty should not be given
- if your child is allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions
Talk to your doctor, pharmacist or nurse before your child is given the vaccine if your child:
- has ever had a severe allergic reaction or breathing problems after any other vaccine injection or after having been given Comirnaty in the past.
- is feeling nervous about the vaccination process or has ever fainted following any needle injection.
- has a severe illness or infection with high fever. However, your child can have the vaccination if he/she have a mild fever or upper airway infection like a cold.

- has a bleeding problem, bruises easily or uses a medicine to prevent blood-clots.
- has a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects the immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty, even after a third dose, may be lower in people who are immunocompromised. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Children
Comirnaty 3 micrograms/dose concentrate for dispersion for injection is not recommended for children aged 5 years to 11 years. There is a paediatric presentation available for infants and children 5 years to 11 years. For details, please refer to the Package Leaflet for Comirnaty 10 micrograms/dose concentrate for dispersion for injection.

Comirnaty is not recommended for infants aged under 6 months.

Other medicines and Comirnaty
Tell your doctor or pharmacist if your child is using, has recently used or might use any other medicines or has recently received any other vaccine.

Pregnancy and breast-feeding
Comirnaty 3 micrograms/dose concentrate for dispersion for injection is not intended for individuals older than 5 years of age.

For details for use in individuals older than 5 years of age, please refer to the Package Leaflet for Comirnaty 30 micrograms/dose concentrate for dispersion for injection, Comirnaty 30 micrograms/dose dispersion for injection or Comirnaty 10 micrograms/dose concentrate for dispersion for injection.

Driving and using machines
Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to use machines or undertake activities such as cycling. Wait until these effects have worn off before resuming activities that require your full attention.

3. How Comirnaty is given

Comirnaty is given after dilution as an injection of 0.2 mL into a muscle of the thigh in infants from 6 to less than 12 months of age. In infants and children 1 year of age or older, Comirnaty is given after dilution as an injection of 0.2 mL into a muscle of the thigh or into a muscle of the upper arm.

Your child will receive 3 injections.

It is recommended to receive the second dose of the same vaccine 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose to complete the vaccination course.

If a child turns 5 years old between their doses in the vaccination course, he/she should complete the series at the same 3 micrograms dose level.

If you have any further questions on the use of Comirnaty, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people
- irritability (6 months to < 2 years)
- injection site: pain/tenderness, swelling
- tiredness
- headache
- drowsiness (6 months to <2 years)
- muscle pain
- chills
- joint pain
- diarrhoea
- fever

Common side effects: may affect up to 1 in 10 people
- nausea
- vomiting
- injection site redness ('very common' in 6 months to 11 years)

Uncommon side effects: may affect up to 1 in 100 people
- enlarged lymph nodes (more frequently observed after the booster dose)
- feeling unwell
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash ('common' for 6 months to < 2 years) or itching
- feeling weak or lack of energy/sleepy
- decreased appetite ('very common' for 6 months to < 2 years)
- excessive sweating
- night sweats

Rare side effects: may affect up to 1 in 1,000 people
- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10,000 people
- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)
- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)

- a skin reaction that causes red spots or patches on the skin, that may look like a target or "bulls-eye" with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoaesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects
If your child gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal and include batch/Lot number if available. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Comirnaty

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 2 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Once removed from the freezer, the unopened vial may be stored and transported refrigerated at 2 °C to 8 °C for up to 10 weeks; not exceeding the printed expiry date (EXP). The outer carton should be marked with the new discard date at 2 °C to 8 °C. Once thawed, the vaccine cannot be re-frozen.

Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8 °C and 30 °C.

Thawed vials can be handled in room light conditions.

After dilution, store the vaccine at 2 °C to 30 °C and use within 12 hours, which includes up to 6 hours transportation time. Discard any unused vaccine.

Do not use this vaccine if you notice particulates in the dilution or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Comirnaty contains

- The active substance is COVID-19 mRNA Vaccine called tozinameran. After dilution, the vial contains 10 doses of 0.2 mL with 3 micrograms tozinameran each.
- The other ingredients are:
  - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
  - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
  - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
  - cholesterol
  - trometamol
  - trometamol hydrochloride
  - sucrose
  - water for injections

What Comirnaty looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in a multidose vial of 10 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a maroon flip-off plastic cap with aluminium seal.

Pack sizes: 10 vials

Not all pack sizes may be marketed.

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Scan the code with a mobile device to get the package leaflet in different languages.

URL: www.comirnatyglobal.com

Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu.

This package leaflet is available in all EU/EEA languages on the European Medicines Agency website.

The following information is intended for healthcare professionals only:

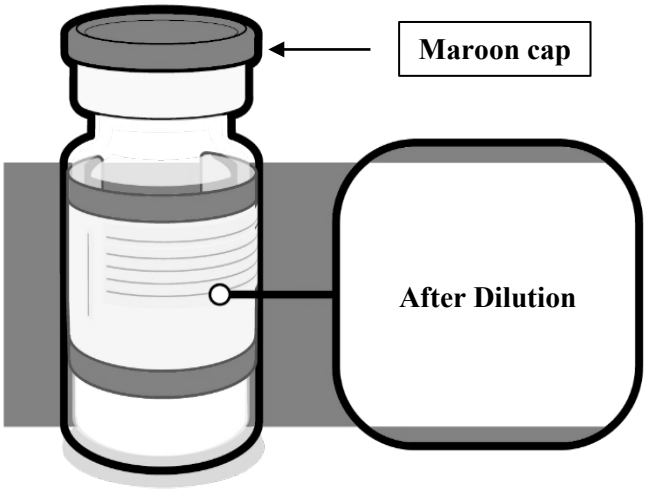
Administer Comirnaty intramuscularly after dilution as a course of 3 doses (0.2 mL each); the second dose of the same vaccine administered 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose to complete the vaccination course.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions
Comirnaty 3 micrograms/dose should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

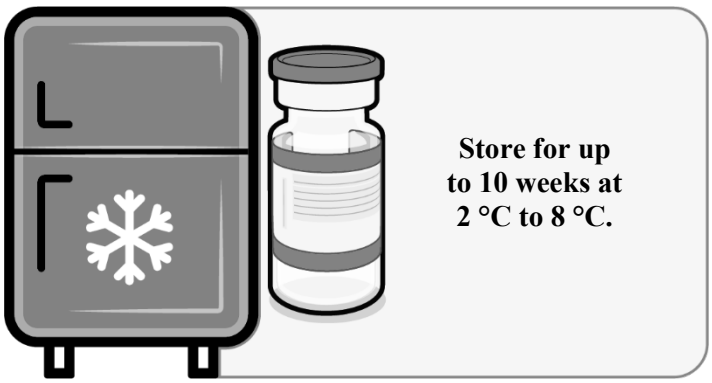
VIAL VERIFICATION OF COMIRNATY 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)



3 mcg

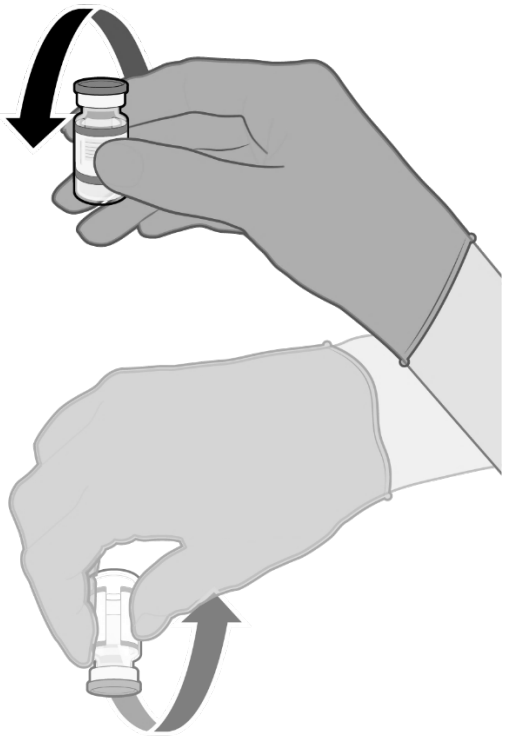
- Verify that the vial has a maroon plastic cap.
- If the vial has a purple plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 30 micrograms/dose concentrate for dispersion for injection.
- If the vial has a grey plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 30 micrograms/dose dispersion for injection, Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection, or Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection.
- If the vial has an orange plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 10 micrograms/dose concentrate for dispersion for injection or Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection.

HANDLING PRIOR TO USE OF COMIRNATY 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)



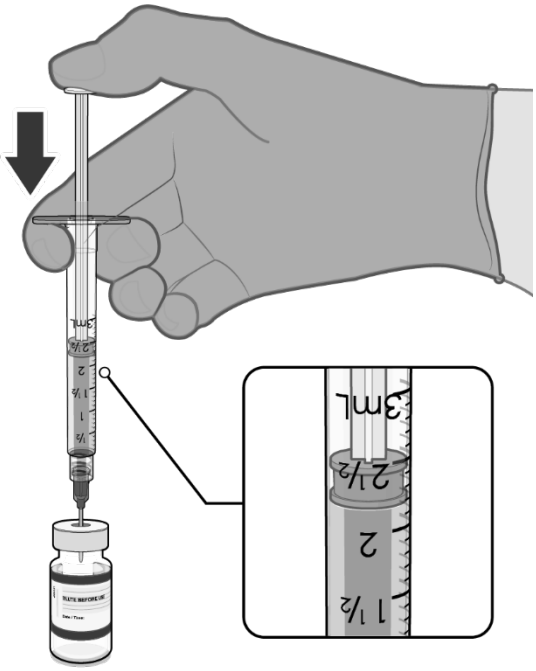
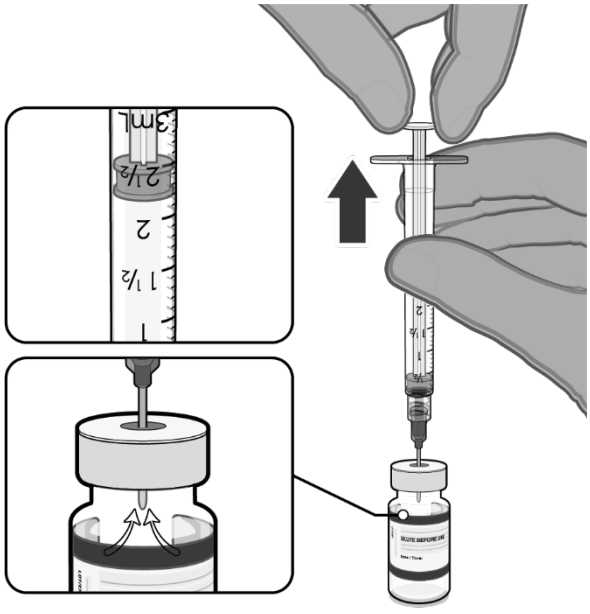
- If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10 vial pack may take 2 hours to thaw. Ensure vials are completely thawed prior to use.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton.
- Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C; not exceeding the printed expiry date (EXP).
- Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C.
- Prior to use, the unopened vial can be stored for up to 12 hours at temperatures up to 30 °C. Thawed vials can be handled in room light conditions.

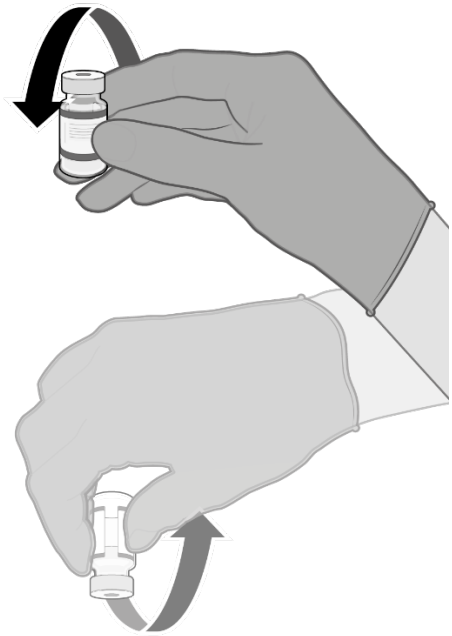
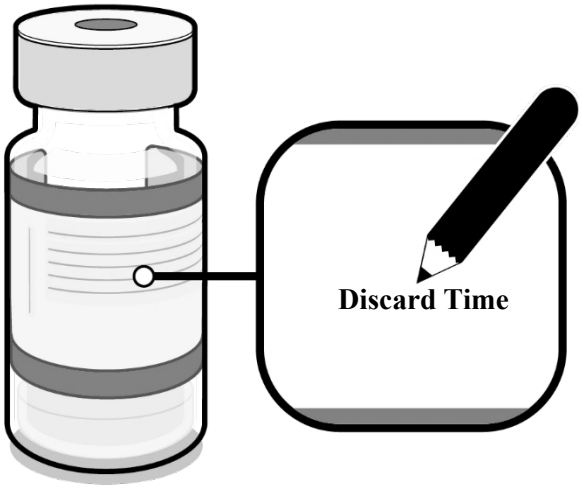
MIXING PRIOR TO DILUTION OF COMIRNATY 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)



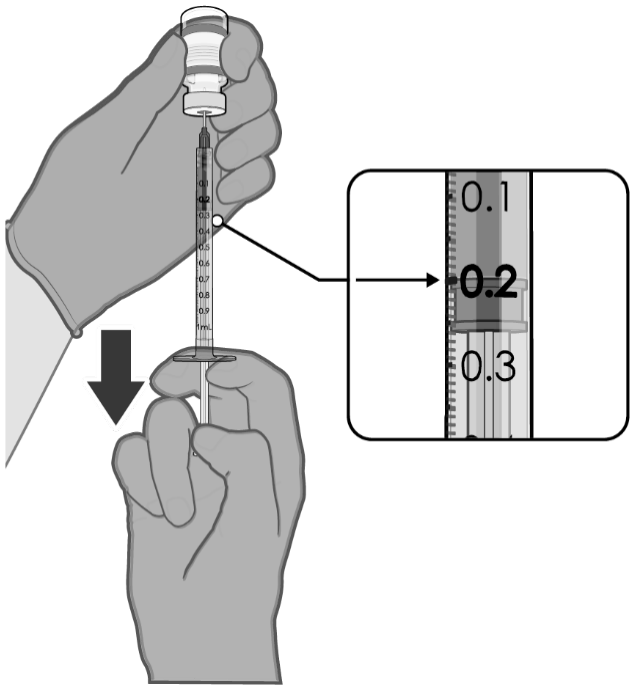
Gently × 10

- Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
- Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.

DILUTION OF COMIRNATY 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)	
 **2.2 mL of sodium chloride 9 mg/mL (0.9%) solution for injection.**	• The thawed vaccine must be diluted in its original vial with 2.2 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.
 **Pull back plunger to 2.2 mL to remove air from vial.**	• Equalise vial pressure before removing the needle from the vial stopper by withdrawing 2.2 mL air into the empty diluent syringe.

 **Gently × 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
 **Record appropriate date and time.** **Use within 12 hours after dilution.**	• The diluted vials should be marked with the appropriate date and time. • After dilution, store at 2 ºC to 30 ºC and use within 12 hours. • Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

PREPARATION OF INDIVIDUAL 0.2 mL DOSES OF COMIRNATY 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)



0.2 mL diluted vaccine

- After dilution, the vial contains 2.6 mL from which 10 doses of 0.2 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.2 mL of Comirnaty for infants and children age 6 months to 4 years.

  Low dead-volume syringes and/or needles should be used in order to extract 10 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres.

  If standard syringes and needles are used, there may not be sufficient volume to extract ten doses from a single vial.
- Each dose must contain 0.2 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
- Discard any unused vaccine within 12 hours after dilution.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Fuljett ta' tagħrif: Informazzjoni għall-utent

Comirnaty 3 mikrogrammi/doża konċentrat għal dispersjoni għall-injezzjoni
Trabi u tfal minn 6 xhur sa 4 snin
Vaċċin tal-mRNA tal-COVID-19 (b'nucleoside modifikat)
tozinameran

▼Dan il-prodott mediċinali huwa suġġett għal monitoraġġ addizzjonali. Dan ser jippermetti identifikazzjoni ta' malajr ta' informazzjoni ġdida dwar is-sigurtà. Inti tista' tgħin billi tirrapporta kwalunkwe effett sekondarju li jista' jkollu/ha t-tifel jew it-tifla tiegħek. Ara t-tmiem ta' sezzjoni 4 biex tara kif għandek tirrapporta effetti sekondarji.

Aqra sew dan il-fuljett kollu qabel tirċievi dan il-vaċċin peress li fih informazzjoni importanti għalik.
- Żomm dan il-fuljett. Jista' jkollok bżonn terġa' taqrah.
- Jekk ikollok aktar mistoqsijiet, staqsi lit-tabib, lill-ispiżjar jew lill-infermier tiegħek.
- Jekk it-tifel jew it-tifla tiegħek ikollu/ha xi effett sekondarju kellem lit-tabib, lill-ispiżjar jew lill-infermier tiegħek. Dan jinkludi xi effett sekondarju possibbli li mhuwiex elenkat f'dan il-fuljett. Ara sezzjoni 4.

F'dan il-fuljett

1. X'inhu Comirnaty u għalxiex jintuża
2. X'għandek tkun taf qabel ma t-tifel jew it-tifla tiegħek jirċievi/tirċievi Comirnaty
3. Kif jingħata Comirnaty
4. Effetti sekondarji possibbli
5. Kif taħżen Comirnaty
6. Kontenut tal-pakkett u informazzjoni oħra

1. X'inhu Comirnaty u għalxiex jintuża

Comirnaty huwa vaċċin użat għall-prevenzjoni tal-COVID-19 ikkawżata minn SARS-CoV-2.

Comirnaty 3 mikrogrammi/doża konċentrat għal dispersjoni għall-injezzjoni jingħata lil trabi u tfal b'età minn 6 xhur sa 4 snin.

Il-vaċċin jikkawża s-sistema immuni (id-difiżi naturali tal-ġisem) biex tipproduċi antikorpi u ċelluli tad-demm li jaħdmu kontra l-virus, u b'hekk tagħti protezzjoni kontra l-COVID-19.

Peress li Comirnaty ma fihx il-virus biex jipproduċi l-immunità, ma jistax jagħti COVID-19 lit-tifel jew lit-tifla tiegħek.

2. X'għandek tkun taf qabel ma t-tifel jew it-tifla tiegħek jirċievi/tirċievi Comirnaty

Comirnaty m'għandux jingħata
- jekk it-tifel jew it-tifla tiegħek huwa/hija allerġiku/a għas-sustanza attiva jew għal xi sustanza oħra ta' din il-mediċina (imniżżla fis-sezzjoni 6)

Twissijiet u prekawzjonijiet
Kellem lit-tabib, lill-ispiżjar jew lill-infermier tiegħek qabel ma t-tifel jew it-tifla tiegħek jingħata/tingħata dan il-vaċċin jekk it-tifel/tifla tiegħek:

- qatt kellu/kellha reazzjoni allerġika severa jew problemi bin-nifs wara l-injezzjoni ta' kwalunkwe vaċċin ieħor jew wara li ngħata/ingħatat Comirnaty fil-passat.
- qed iħossu/iħossha nervuż/a dwar il-proċess tat-tilqim jew jekk xi darba intilef/intilfet minn sensih/ha wara kwalunkwe injezzjoni b'labra.
- għandu/għandha marda severa jew infezzjoni b'deni għoli. Madankollu, it-tifel/tifla tiegħek jista'/tista' jieħu/tieħu t-tilqima tiegħek jekk ikollu/ha deni ħafif jew infezzjoni ħafifa tal-parti ta' fuq tal-passaġġ tan-nifs bħal riħ.
- għandu/għandha problema ta' ħruġ ta' demm, jitbenġel/titbenġel malajr jew juża/tuża mediċina biex tipprevjeni emboli tad-demm.
- għandu/għandha sistema immuni mdgħajfa, minħabba marda bħal infezzjoni bl-HIV jew mediċina bħal kortikosterojdi li taffettwa s-sistema immuni.

Hemm żieda fir-riskju ta' mijokardite (infjammazzjoni tal-muskolu tal-qalb) u perikardite (infjammazzjoni tar-rita barra mill-qalb) wara tilqim b'Comirnaty (ara sezzjoni 4). Dawn il-kundizzjonijiet jistgħu jiżviluppaw fi żmien ftit jiem biss wara t-tilqim u seħħew primarjament fi żmien 14-il jum. Dawn ġew osservati aktar spiss wara t-tieni tilqima, u aktar spiss f'irġiel iżgħar fl-età. Ir-riskju ta' mijokardite u perikardite jidher li huwa aktar baxx fi tfal b'età minn 5 snin sa 11-il sena meta mqabbla mal-etajiet ta' 12-il sena sa 17-il sena. Wara t-tilqim, għandek toqgħod attent għal sinjali ta' mijokardite u perikardite, bħal qtugħ ta' nifs, palpitazzjonijiet u wġigħ fis-sider, u tfittex attenzjoni medika immedjata jekk dawn iseħħu.

Bħal kull vaċċin, Comirnaty jista' ma jipproteġix b'mod sħiħ lil dawk kollha li jirċevuh u mhux magħruf kemm ser iddum protett.

L-effikaċja ta' Comirnaty, anke wara t-tielet doża, tista' tkun aktar baxxa f'nies li huma immunokompromessi. F'dawn il-każijiet, għandek tkompli tieħu prekawzjonijiet fiżiċi biex tgħin tipprevjeni l-COVID-19. Barra minn hekk, persuni viċin tiegħek għandhom jiġu mlaqqma kif xieraq. Iddiskuti rakkomandazzjonijiet individwali xierqa mat-tabib tiegħek.

Tfal
Comirnaty 3 mikrogrammi/doża konċentrat għal dispersjoni għall-injezzjoni mhux rakkomandat għal tfal b'età minn 5 snin sa 11-il sena. Hemm preżentazzjoni pedjatrika disponibbli għal trabi u tfal b'età minn 5 snin sa 11-il sena. Għad-dettalji, jekk jogħġbok irreferi għall-Fuljett ta' Tagħrif ta' Comirnaty 10 mikrogrammi/doża konċentrat għal dispersjoni għall-injezzjoni.

Comirnaty mhux rakkomandat għal trabi b'età ta' inqas minn 6 xhur.

Mediċini oħra u Comirnaty
Għid lit-tabib jew lill-ispiżjar tiegħek jekk it-tifel/tifla tiegħek qed juża/tuża, uża/użat dan l-aħħar jew jista'/tista' juża/tuża xi mediċini oħra jew jekk riċentement irċieva/irċeviet xi vaċċin ieħor.

Tqala u treddigħ
Comirnaty 3 mikrogrammi/doża konċentrat għal dispersjoni għall-injezzjoni mhuwiex maħsub għal individwi li għandhom aktar minn 5 snin.

Għal dettalji dwar l-użu f'individwi b'età ta' aktar minn 5 snin, jekk jogħġbok irreferi għall-Fuljett ta' Tagħrif ta' Comirnaty 30 mikrogramma/doża konċentrat għal dispersjoni għall-injezzjoni, Comirnaty

30 mikrogramma/doża dispersjoni għall-injezzjoni jew Comirnaty 10 mikrogrammi/doża konċentrat għal dispersjoni għall-injezzjoni.

Sewqan u tħaddim ta' magni
Uħud mill-effetti tat-tilqima msemmija fis-sezzjoni 4 (Effetti sekondarji possibbli) jistgħu jaffettwaw b'mod temporanju l-ħila tiegħek li tħaddem magni jew li twettaq attivitajietbħal issuq rota. Stenna sakemm dawn l-effetti jgħaddu qabel ma tkompli b'attivitajiet li jeħtieġu l-attenzjoni sħiħa tiegħek.

3. Kif jingħata Comirnaty

Comirnaty jingħata wara d-dilwizzjoni bħala injezzjoni ta' 0.2 mL ġo muskolu fil-koxxa fi trabi b'età minn 6 xhur sa anqas minn 12-il xahar. Fi trabi u tfal ta' sena jew aktar, Comirnaty jingħata wara d-dilwizzjoni bħala injezzjoni ta' 0.2 mL f'muskolu fil-koxxa jew f'muskolu fin-naħa ta' fuq tad-driegħ.

It-tifel/tifla tiegħek ser jirċievi/tirċievi 3 injezzjonijiet.

Huwa rakkomandat li tirċievi t-tieni doża tal-istess vaċċin 3 ġimgħat wara l-ewwel doża segwit mit-tielet doża mill-inqas 8 ġimgħat wara t-tieni doża biex tlesti l-kors ta' tilqim.

Jekk tifel/tifla jagħlqu 5 snin bejn id-dożi tagħhom waqt il-kors tat-tilqim, huwa/hija għandhom ikomplu s-serje fl-istess livell tad-doża ta' 3 mikrogrammi.
Jekk għandek aktar mistoqsijiet dwar l-użu ta' Comirnaty, staqsi lit-tabib, lill-ispiżjar jew lill-infermier tiegħek.

4. Effetti sekondarji possibbli

Bħal kull vaċċin ieħor, Comirnaty jista' jikkawża effetti sekondarji, għalkemm ma jidhrux f'kulħadd.

Effetti sekondarji komuni ħafna: jistgħu jaffettwaw aktar minn persuna waħda minn kull 10
- irritabilità (6 xhur sa < sentejn)
- sit tal-injezzjoni: uġigħ/sensittività, nefħa
- għeja
- uġigħ ta' ras
- ħedla ta' ngħas (6 xhur sa < sentejn)
- uġigħ fil-muskoli
- tkexkix ta' bard
- uġigħ fil-ġogi
- dijarea
- deni

Effetti sekondarji komuni: jistgħu jaffettwaw sa persuna waħda minn kull 10
- dardir
- rimettar
- ħmura fis-sit tal-injezzjoni ('komuni ħafna' fl-età ta' 6 xhur sa 11-il sena)

Effetti sekondarji mhux komuni: jistgħu jaffettwaw sa persuna waħda minn kull 100
- glandoli limfatiċi minfuħa (osservati b'mod aktar frekwenti wara d-doża *booster*)
- tħossok ma' tiflaħx

- uġigħ fid-dirgħajn
- insomnja
- ħakk fis-sit tal-injezzjoni
- reazzjonijiet allerġiċi bħal raxx (‘komuni’ fl-età ta’ 6 xhur sa < sentejn) jew ħakk
- tħossok dgħajjef jew b’nuqqas ta’ enerġija/bi ngħas
- tnaqqis fl-aptit (‘komuni ħafna’ fl-età ta’ 6 xhur sa < sentejn)
- għaraq eċċessiv
- għaraq matul il-lejl

Effetti sekondarji rari: jistgħu jaffettwaw sa persuna waħda minn kull 1,000
- naħa waħda tal-wiċċ tiddendel b’mod temporanju
- reazzjonijiet allerġiċi bħal ħorriqija jew nefħa fil-wiċċ

Effetti sekondarji rari ħafna: jistgħu jaffettwaw sa persuna waħda minn kull 10,000
- infjammazzjoni tal-muskolu tal-qalb (mijokardite) jew infjammazzjoni tar-rita barra mill-qalb (perikardite) li tista’ tirriżulta fi qtugħ ta’ nifs, palpitazzjonijiet jew uġigħ fis-sider

Mhux magħruf (ma tistax tittieħed stima mid-*data* disponibbli)
- reazzjoni allerġika severa
- nefħa estensiva fid-driegħ li fih ingħata l-vaċċin
- nefħa fil-wiċċ (nefħa fil-wiċċ tista’ sseħħ f’pazjenti li kellhom *fillers* dermali tal-wiċċ)
- reazzjoni tal-ġilda li tikkawża tikek jew rqajja’ ħomor fuq il-ġilda, li jistgħu jidhru bħal targit jew “bulls-eye” b’ċentru aħmar skur imdawwar bi ċrieki ħomor ċari (eritema multiforme)
- sensazzjoni mhux tas-soltu fil-ġilda, bħal tnemnim jew sensazzjoni ta’ xi ħaġa miexja fuq il-ġilda (parestesija)
- tnaqqis fis-sensazzjoni jew fis-sensittività, speċjalment fil-ġilda (ipoestesija)
- emorraġija mestrwali qawwija (il-parti l-kbira tal-każijiet dehru li ma kinux serji u kienu ta’ natura temporanja)

Rappurtar tal-effetti sekondarji
Jekk it-tifel/tifla tiegħek ikollu/ha xi effett sekondarju, kellem lit-tabib, lill-ispiżjar jew lill-infermier tiegħek. Dan jinkludi xi effett sekondarju possibbli li mhuwiex elenkat f’dan il-fuljett. Tista’ wkoll tirrapporta effetti sekondarji direttament permezz tas-sit elettroniku tar-rapportar tar-reazzjonijiet avversi suspettati: www.medicinesauthority.gov.mt/adrportal u inkludi n-numru tal-lott/Lott jekk disponibbli. Billi tirrapporta l-effetti sekondarji tista’ tgħin biex tiġi pprovduta aktar informazzjoni dwar is-sigurtà ta’ din il-mediċina.

5. Kif taħżen Comirnaty

Żomm din il-mediċina fejn ma tidhirx u ma tintlaħaqx mit-tfal.

It-tagħrif li ġej dwar il-ħażna, d-data ta’ meta tiskadi u l-użu u l-immaniġġar huwa maħsub għall-professjonisti tal-kura tas-saħħa.

Tużax din il-mediċina wara d-data ta’ meta tiskadi li tidher fuq il-kartuna u t-tikketta wara JIS. Id-data ta’ meta tiskadi tirreferi għall-aħħar ġurnata ta’ dak ix-xahar.

Aħżen fil-friża f’temperatura ta’ -90 °C sa -60 °C.

Aħżen fil-pakkett oriġinali sabiex tilqa' mid-dawl.

Il-vaċċin se jiġi riċevut ffriżat f'temperatura ta' -90 °C sa -60 °C. Wara li jiġi riċevut vaċċin iffriżat jista' jinħażen f'temperatura ta' -90 °C sa -60 °C jew f'temperatura ta' 2 °C sa 8 °C.

Meta jinħażnu ffriżati f'temperatura ta' -90 °C sa -60 °C, pakketti b'10 kunjetti tal-vaċċin jistgħu jinħallu mis-silġ f'temperatura ta' 2 °C sa 8 °C għal sagħtejn jew kunjetti individwali jistgħu jinħallu f'temperatura tal-kamra (sa 30 °C) għal 30 minuta.

Ladarba jitneħħa mill-friża, il-kunjett mhux miftuħ jista' jinħażen u jiġi ttrasportat fi friġġ f'temperatura ta' 2 °C sa 8 °C għal perjodu massimu ta' 10 ġimgħat; dan m'għandux jaqbeż id-data ta' meta jiskadi stampata (JIS). Il-kartuna ta' barra għandha tiġi mmarkata bid-data l-ġdida li fiha għandu jintrema jekk jinħażen f'temperatura ta' 2 °C sa 8 °C. Ladarba jinħall mis-silġ, il-vaċċin ma jistax jiġi ffriżat mill-ġdid.

Qabel l-użu, il-kunjetti mhux miftuħa jistgħu jinħażnu għal massimu ta' 12-il siegħa f'temperaturi bejn 8 °C u 30 °C.

Kunjetti li nħallu mis-silġ jistgħu jiġu mmaniġġjati f'kondizzjonijiet ta' dawl tal-kamra.

Wara d-dilwizzjoni, aħżen il-vaċċin f'temperatura ta' 2 °C sa 30 °C u użah fi żmien 12-il siegħa, dan jinkludi sa 6 sigħat li matulhom il-prodott jiġi trasportat. Armi kwalunkwe vaċċin mhux użat.

Tużax dan il-vaċċin jekk tinnota partiċelli fid-dilwizzjoni jew bidla fil-kulur.

Tarmix mediċini mal-ilma tad-dranaġġ jew mal-iskart domestiku. Staqsi lill-ispiżjar tiegħek dwar kif għandek tarmi mediċini li m'għadekx tuża. Dawn il-miżuri jgħinu għall-protezzjoni tal-ambjent.

6. Kontenut tal-pakkett u informazzjoni oħra

X'fih Comirnaty

- Is-sustanza attiva hi Vaċċin tal-mRNA tal-COVID-19 imsejħa tozinameran. Wara d-dilwizzjoni, il-kunjett ikun fih 10 doži ta' 0.2 mL bi 3 mikrogrammi ta' tozinameran kull wieħed.
- Is-sustanzi mhux attivi l-oħra huma:
  - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
  - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
  - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
  - kolesterol
  - trometamol
  - trometamol hydrochloride
  - sucrose
  - ilma għall-injezzjonijiet

Kif jidher Comirnaty u l-kontenut tal-pakkett

Il-vaċċin huwa dispersjoni ta' lewn abjad sa abjad maħmuġ (pH: 6.9 - 7.9) ipprovdut f'kunjett b'aktar minn doża waħda ta' 10 doži f'kunjett trasparenti ta' 2 mL (ħġieġ tat-tip I), b'tapp tal-lastku u għatu tal-plastik marun li jitneħħa b'daqqa ta' saba' b'siġill tal-aluminju.

Daqsijiet tal-pakkett: 10 kunjetti

Jista' jkun li mhux il-pakketti tad-daqsijiet kollha jkunu fis-suq.

Detentur tal-Awtorizzazzjoni għat-Tqegħid fis-Suq
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz
Il-Ġermanja
Phone: +49 6131 9084-0
Fax: +49 6131 9084-2121
service@biontech.de

Manifatturi
BioNTech Manufacturing GmbH
Kupferbergterrasse 17 - 19
55116 Mainz
Il-Ġermanja

Pfizer Manufacturing Belgium NV
Rijksweg 12
2870 Puurs
Il-Belġju

Għal kull tagħrif dwar din il-mediċina, jekk jogħġbok ikkuntattja lir-rappreżentant lokali tad-Detentur tal-Awtorizzazzjoni għat-Tqegħid fis-Suq:

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România
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Slovenija
Pfizer Luxembourg SARL
Pfizer, podružnica za svetovanje s področja farmacevtske dejavnosti, Ljubljana
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Slovenská republika
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Sverige
Pfizer AB
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United Kingdom (Northern Ireland)
Pfizer Limited
Tel: +44 (0) 1304 616161

Dan il-fuljett kien rivedut l-aħħar f’ 11/2022.

Skennja l-kowd b’*mobile* biex tikseb il-fuljett ta’ tagħrif f’lingwi differenti.

URL: www.comirnatyglobal.com

Informazzjoni dettaljata dwar din il-mediċina tinsab fuq is-sit elettroniku tal-Aġenzija Ewropea għall-Mediċini: http://www.ema.europa.eu.

Dan il-fuljett huwa disponibbli fil-lingwi kollha tal-UE/ŻEE fis-sit elettroniku tal-Aġenzija Ewropea għall-Mediċini.

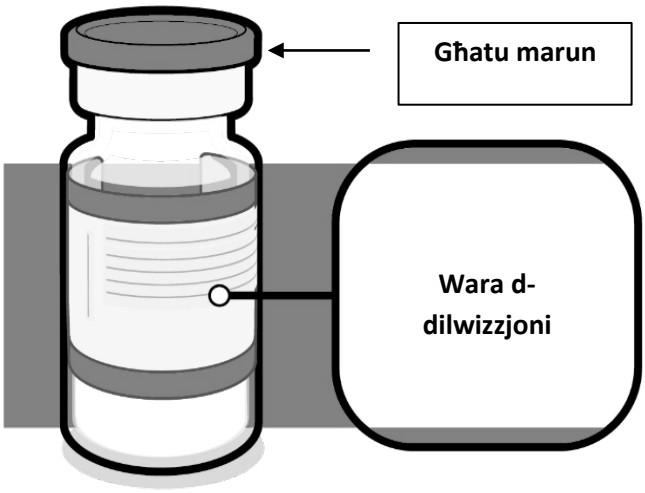
It-tagħrif li jmiss qed jingħata biss għall-professjonisti tal-kura tas-saħħa biss:

Agħti Comirnaty ġol-muskoli wara d-dilwizzjoni bħala kors ta' 3 dożi (0.2 mL kull waħda); it-tieni doża tal-istess vaċċin mogħtija 3 ġimgħat wara l-ewwel doża segwita mit-tielet doża mill-inqas 8 ġimgħat wara t-tieni doża biex jitlesta l-kors tat-tilqim.

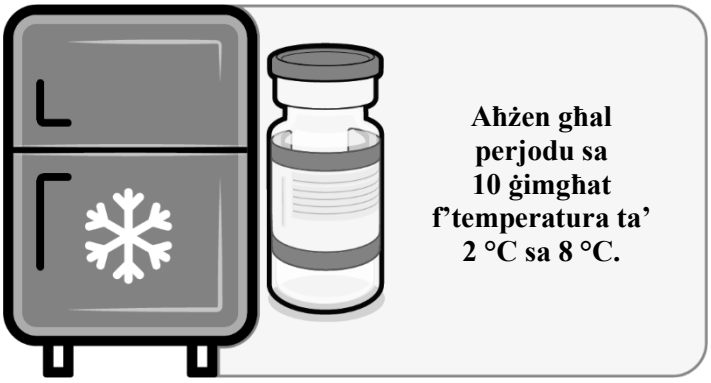
Traċċabilità

Sabiex tittejjeb it-traċċabilità tal-prodotti mediċinali bijoloġiċi, l-isem u n-numru tal-lott tal-prodott amministrat għandhom jiġu rrekordjati b'mod ċar.

Istruzzjonijiet dwar l-immaniġġar
Comirnaty 3 mikrogrammi/doża għandu jiġi ppreparat minn professjonist tal-kura tas-saħħa permezz ta' teknika asettika biex tiġi żgurata l-isterilità tad-dispersjoni ppreparata.

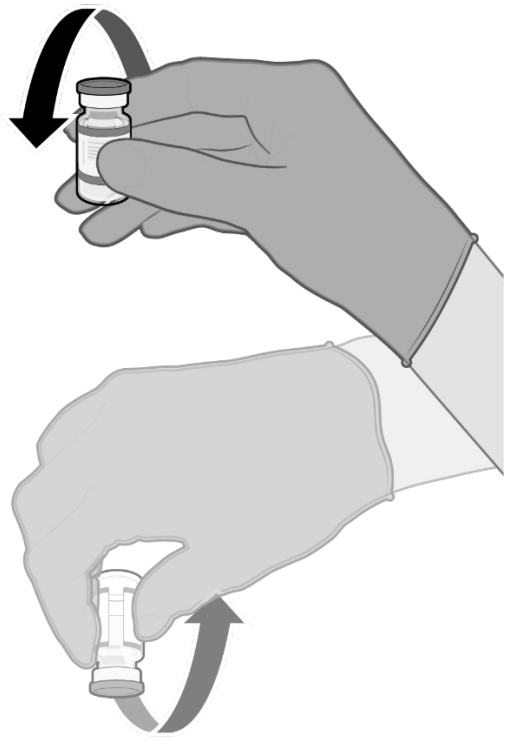
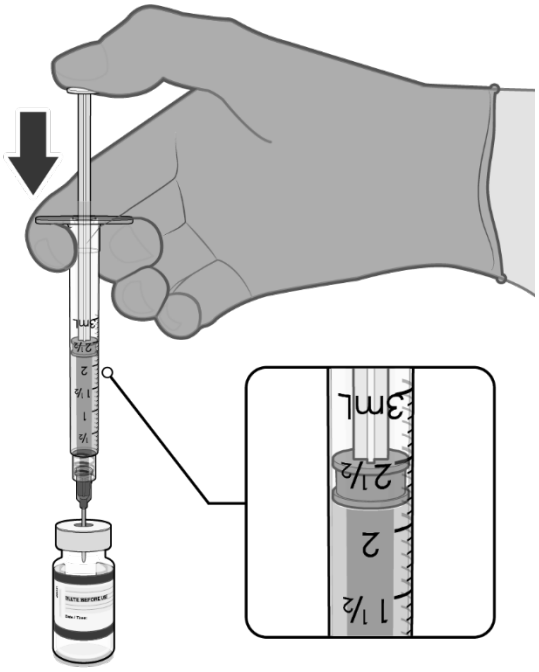
VERIFIKA TAL-KUNJETT TA' COMIRNATY 3 MIKROGRAMMI/DOŻA KONĊENTRAT GĦAL DISPERSJONI GĦALL-INJEZZJONI (TRABI U TFAL MINN 6 XHUR SA 4 SNIN)	
 **3 mcg**	• Ivverifika li l-kunjett għandu għatu tal-plastik marun. • Jekk il-kunjett għandu għatu tal-plastik vjola, jekk jogħġbok irreferi għas-Sommarju tal-Karatteristiċi tal-Prodott għal Comirnaty 30 mikrogramma/doża konċentrat għal dispersjoni għall-injezzjoni. • Jekk il-kunjett għandu għatu tal-plastik griż, jekk jogħġbok irreferi għas-Sommarju tal-Karatteristiċi tal-Prodott għal Comirnaty 30 mikrogramma/doża dispersjoni għall-injezzjoni, Comirnaty Original/Omicron BA.1 (15/15 mikrogramma)/doża dispersjoni għall-injezzjoni, jew Comirnaty Original/Omicron BA.4-5 (15/15 mikrogramma)/doża dispersjoni għall-injezzjoni. • Jekk il-kunjett għandu għatu tal-plastik oranġjo, jekk jogħġbok irreferi għas-Sommarju tal-Karatteristiċi tal-Prodott għal Comirnaty 10 mikrogrammi/doża konċentrat għal dispersjoni għall-injezzjoni jew Comirnaty Original/Omicron BA.4-5 (5/5 mikrogrammi)/doża konċentrat għal dispersjoni għall-injezzjoni.

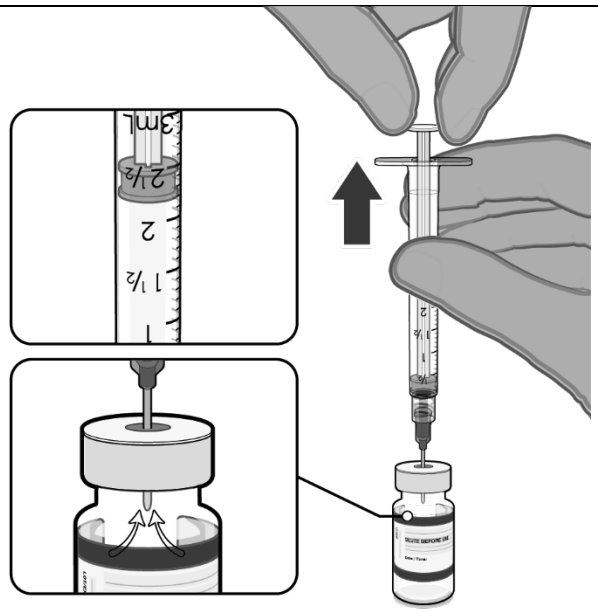
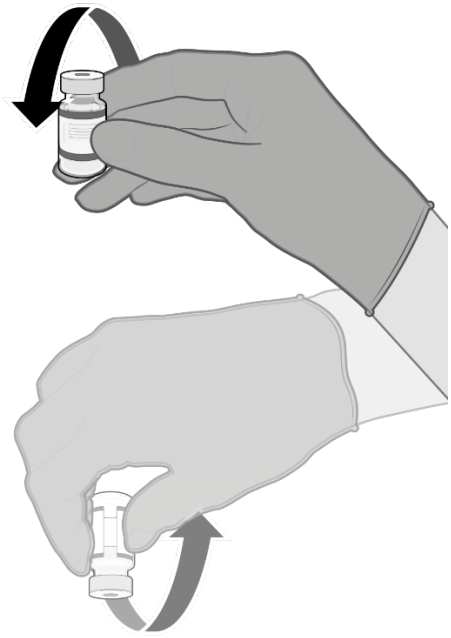
IMMANIĠĠAR QABEL L-UŻU TA’ COMIRNATY 3 MIKROGRAMMI/DOŻA KONĊENTRAT GĦAL DISPERSJONI GĦALL-INJEZZJONI (TRABI U TFAL MINN 6 XHUR SA 4 SNIN)

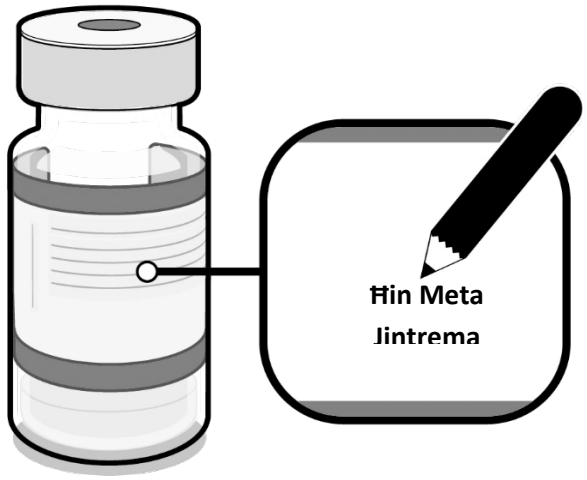


- Jekk il-kunjett b’aktar minn doża waħda jinħażen iffriżat għandu jinħall mis-silġ qabel l-użu. Kunjetti ffriżati għandhom jiġu ttrasferiti għal ambjent b’temperatura ta’ 2 °C sa 8 °C biex jinħallu mis-silġ; pakkett ta’ 10 kunjetti jista’ jieħu sagħtejn biex jinħall mis-silġ. Kun ċert li l-kunjetti jkunu nħallu kompletament mis-silġ qabel l-użu.
- Meta l-kunjetti jitmexxew għal ħażna f’temperatura ta’ 2 °C sa 8 °C, aġġorna d-data ta’ meta jiskadi fuq il-kartuna.
- Kunjetti mhux miftuħa jistgħu jinħażnu għal massimu ta’ 10 ġimgħat f’temperatura ta’ 2 °C sa 8 °C; dan m’għandux jaqbeż id-data ta’ meta jiskadi stampata (JIS).
- Inkella, kunjetti ndividwali ffriżati jistgħu jinħallu mis-silġ għal 30 minuta f’temperaturi sa 30 °C.
- Qabel l-użu, il-kunjett mhux miftuħ jista’ jinħażen għal perjodu sa 12-il siegħa f’temperaturi sa 30 °C. Kunjetti li nħallu mis-silġ jistgħu jiġu mmaniġġjati f’kondizzjonijiet ta’ dawl tal-kamra.

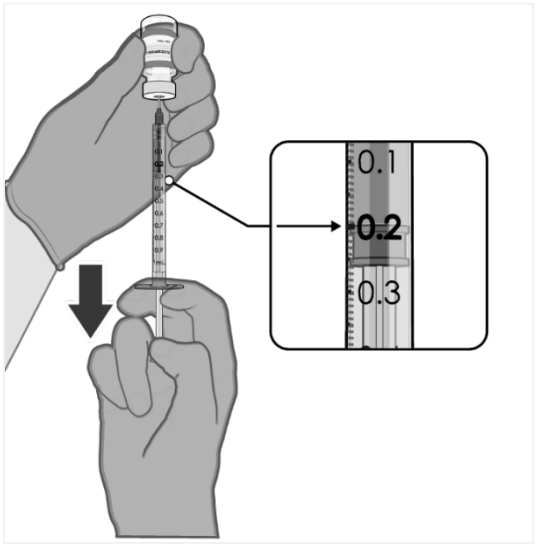
TAĦLIT QABEL ID-DILWIZZJONI TA’ COMIRNATY 3 MIKROGRAMMI/DOŻA KONĊENTRAT GĦAL DISPERSJONI GĦALL-INJEZZJONI (TRABI U TFAL MINN 6 XHUR SA 4 SNIN)

 **Bil-mod × 10**	• Ħalli l-kunjett li jkun inħall mis-silġ jilħaq it-temperatura tal-kamra u aqilbu bil-mod ta’ taħt fuq għal 10 darbiet qabel id-dilwizzjoni. Tħawwadx. • Qabel id-dilwizzjoni, id-dispersjoni li tkun inħallet mis-silġ jista’ jkun fiha partiċelli amorfi opaki ta’ lewn abjad sa abjad maħmuġ.
DILWIZZJONI TA’ COMIRNATY 3 MIKROGRAMMI/DOŻA KONĊENTRAT GĦAL DISPERSJONI GĦALL-INJEZZJONI (TRABI U TFAL MINN 6 XHUR SA 4 SNIN)	
 **2.2 mL ta’ soluzzjoni għall-injezzjoni ta’ 9 mg/mL (0.9%) sodium chloride.**	• It-tilqima li tkun inħallet mis-silġ għandha tiġi dilwita fil-kunjett oriġinali tagħha b’2.2 mL ta’ soluzzjoni għall-injezzjoni ta’ 9 mg/mL (0.9%) sodium chloride, bl-użu ta’ labra b’daqs ta’ 21 gauge jew idjaq u tekniki asettiċi.

 **Iġbed il-planġer lura sa 2.2 mL biex tneħħi l-arja mill-kunjett.**	• Ugwalizza l-pressjoni fil-kunjett qabel ma tneħħi l-labra mit-tapp tal-kunjett billi tiġbed 2.2 mL ta’ arja fis-siringa tad-dilwent vojta.
 **Bil-mod × 10**	• Aqleb id-dispersjoni dilwita ta’ taħt fuq bil-mod għal 10 darbiet. Tħawwadx. • Il-vaċċin dilwit għandu jidher bħala dispersjoni ta’ lewn abjad għal abjad maħmuġ mingħajr l-ebda partiċelli viżibbli. Tużax il-vaċċin dilwit jekk ikun hemm frak jew tibdil fil-kulur.

 **Irreġistra d-data u l-ħin xierqa.** **Uża fi żmien 12-il siegħa wara d-dilwizzjoni.**	• Il-kunjetti dilwiti għandhom jiġu mmarkati bid-data u l-ħin xierqa. • Wara d-dilwizzjoni, aħżen f'temperatura ta' 2 ºC sa 30 ºC u uża fi żmien 12-il siegħa. • Tiffriżax u tħawwadx id-dispersjoni dilwita. Jekk titpoġġa fi friġġ, ħalli id-dispersjoni dilwita tilħaq it-temperatura tal-kamra qabel l-użu.

PREPARAZZJONI TA’ DOŻI INDIVIDWALI TA’ 0.2 mL TA’ COMIRNATY 3 MIKROGRAMMI/DOŻA KONĊENTRAT GĦAL DISPERSJONI GĦALL-INJEZZJONI (TRABI U TFAL MINN 6 XHUR SA 4 SNIN)



Vaċċin dilwit ta’ 0.2 mL

- Wara d-dilwizzjoni, il-kunjett ikun fih 2.6 mL li minnhom jistgħu jinġibdu 10 doži ta’ 0.2 mL.
- Bl-użu ta’ teknika asettika, naddaf it-tapp tal-kunjett b’imselħa antisettika li tintuża darba u tintrema.
- Iġbed 0.2 mL ta’ Comirnaty għal trabi u tfal b’età minn 6 xhur sa 4 snin.

  Sabiex jinġibdu 10 doži minn kunjett wieħed għandhom jintużaw siringi u/jew labar b’volum li ma jistax jintuża żgħir. Il-kombinazzjoni tas-siringa u tal-labra b’volum li ma jistax jintuża żgħir għandu jkollha volum li ma jistax jintuża ta’ mhux aktar minn 35 mikrolitru.

  Jekk jintużaw siringi u labar standard, jista’ ma jkunx hemm volum suffiċjenti biex jinġibdu għaxar doži minn kunjett wieħed.
- Kull doża għandu jkun fiha 0.2 mL ta’ vaċċin.
- Jekk l-ammont ta’ vaċċin li jifdal fil-kunjett ma jistax jipprovdi doża sħiħa ta’ 0.2 mL, armi l-kunjett u kwalunkwe volum żejjed.
- Armi kwalunkwe vaċċin mhux użat fi żmien 12-il siegħa wara d-dilwizzjoni.

Rimi

Kull fdal tal-prodott mediċinali li ma jkunx intuża jew skart li jibqa’ wara l-użu tal-prodott għandu jintrema kif jitolbu l-liġijiet lokali.