Package leaflet: Information for the user

Comirnaty™ 30 micrograms/dose

concentrate for dispersion for injection

Adults and adolescents from 12 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 you 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 you get 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

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

Comirnaty 30 micrograms/dose concentrate for dispersion for injection is given to adults and adolescents from 12 years of age and older.

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 you COVID-19.

2 What you need to know before you receive Comirnaty

Comirnaty should not be given

- if you are 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 you are given the vaccine if:

- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given Comirnaty in the past.
- you are feeling nervous about the vaccination process or have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your 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. 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.

You may receive a third dose of Comirnaty. 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 is not recommended for children aged under 12 years.

Other medicines and Comirnaty

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you receive this vaccine.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

Comirnaty contains potassium and sodium

This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3 How Comirnaty is given

Comirnaty is given after dilution as an injection of 0.3 mL into a muscle of your upper arm.

You will receive 2 injections.

It is recommended to receive the second dose of the same vaccine 3 weeks after the first dose to complete the vaccination course.

A booster dose (third dose) of Comirnaty may be given at least 6 months after the second dose in individuals 18 years of age and older.

If you are immunocompromised, you may receive a third dose of Comirnaty at least 28 days after the second dose.

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

- injection site: pain, swelling
- tiredness
- headache
- muscle pain
- chills
- joint pain
- diarrhoea

- fever

Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.

Common side effects: may affect up to 1 in 10 people
- injection site redness
- nausea
- vomiting

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 or itching
- feeling weak or lack of energy/sleepy
- decreased appetite
- 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)

Reporting of side effects
If you get 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. Within the 9-month shelf life unopened vials may be stored and transported at -25 °C to -15 °C for a single period of up to 2 weeks and can be returned to -90 °C to -60 °C.

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

When stored frozen at -90 °C to -60 °C, 195-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 3 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Transfers of frozen vials stored at ultra-low temperature (< -60 °C)
- Closed-lid vial trays containing 195 vials removed from ultra-low temperature frozen storage (< -60 °C) may be at temperatures up to 25 °C for up to 5 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from ultra-low temperature frozen storage (< -60 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- After vial trays are returned to frozen storage following temperature exposure up to 25 °C, they must remain in frozen storage for at least 2 hours before they can be removed again.

Transfers of frozen vials stored at -25 °C to -15 °C
- Closed-lid vial trays containing 195 vials removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 1 minute.

Once a vial is removed from the vial tray, it should be thawed for use.

After thawing, the vaccine should be diluted and used immediately. However, in-use stability data have demonstrated that once removed from freezer, the undiluted vaccine can be stored for up to 1 month at 2 °C to 8 °C within the 9-month shelf life. Within the 1-month shelf life at 2 °C to 8 °C, up to 12 hours may be used for transportation. Prior to use, the unopened vaccine can be stored for up to 2 hours at temperatures up to 30 °C.

Thawed vials can be handled in room light conditions.

After dilution, store and transport the vaccine at 2 °C to 30 °C and use within 6 hours. Discard any unused vaccine.

Once removed from the freezer and diluted, the vials should be marked with the new discard date and time. Once thawed, the vaccine cannot be re-frozen.

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 6 doses of 0.3 mL with 30 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
  - potassium chloride
  - potassium dihydrogen phosphate
  - sodium chloride
  - disodium phosphate dihydrate
  - sucrose
  - water for injections
  - sodium hydroxide (for pH adjustment)
  - hydrochloric acid (for pH adjustment)

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 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a purple flip-off plastic cap with aluminium seal.

Pack size: 195 vials

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BioNTech Manufacturing GmbH
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Manufacturers

- BioNTech Manufacturing GmbH, Kupferbergterrasse 17 – 19, 55116 Mainz, Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Malta
Vivian Corporation Ltd, Tel: +35621 344610

This leaflet was last revised in 01/2022

This medicine has been given 'conditional approval'. This means that there is more evidence to come about this medicine. The European Medicines Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.

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 web site: 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 primary course of 2 doses (0.3 mL each) 3 weeks apart.
A booster dose (third dose) of Comirnaty may be given at least 6 months after the second dose in individuals 18 years of age and older.

A third dose may be given at least 28 days after the second dose to individuals who are severely immunocompromised.

Traceability

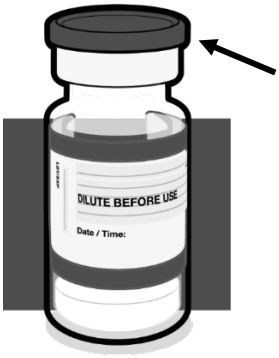
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions

Comirnaty should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

DOSE VERIFICATION OF COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (12 YEARS AND OLDER)

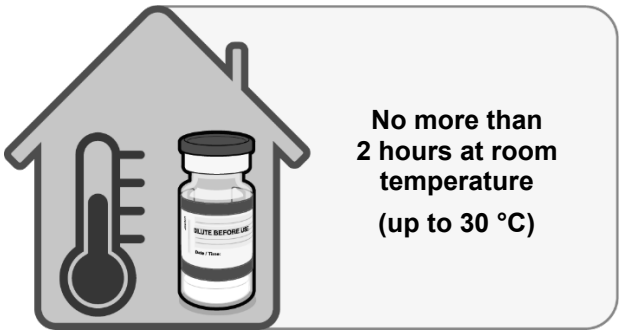
- Verify that the vial has a purple plastic cap.
- If the vial has a grey plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 30 micrograms/dose dispersion for injection.
- If the vial has an orange plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 10 micrograms/dose concentrate for dispersion for injection.



Purple cap

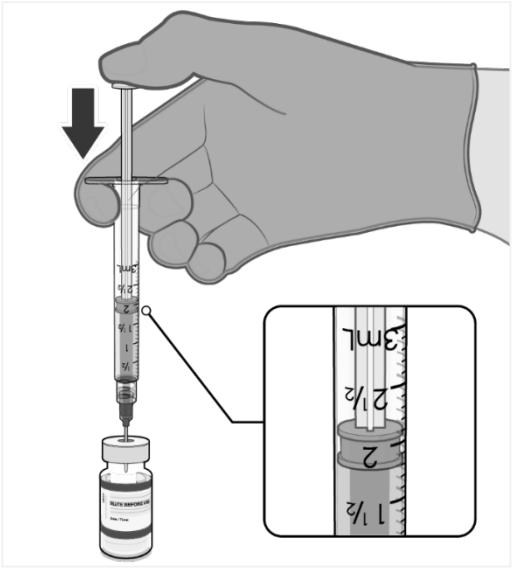
THAWING PRIOR TO DILUTION OF COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (12 YEARS AND OLDER)

- The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use.
- The unopened vial can be stored for up to 1 month at 2 °C to 8 °C within the 9-month shelf life. Within the 1-month shelf life at 2 °C to 8 °C, up to 12 hours may be used for transportation.
- Allow the thawed vial to come to room temperature. Prior to use, the unopened vial can be stored for up to 2 hours at temperatures up to 30 °C. Thawed vials can be handled in room light conditions.
- Gently invert the vial 10 times prior to dilution. Do not shake.
- Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.



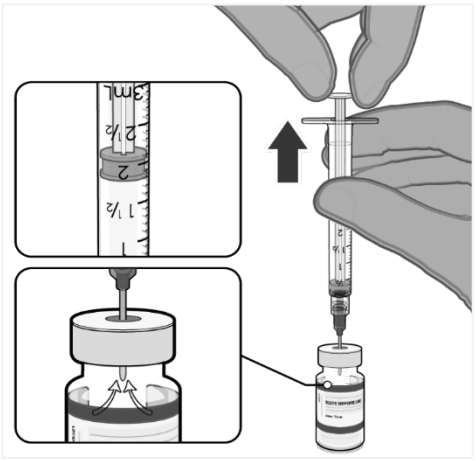
DILUTION OF COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (12 YEARS AND OLDER)

- The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.



1.8 mL of 0.9% sodium chloride iniection

- Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.



Pull back plunger to 1.8 mL to remove air from vial.

- Gently invert the diluted dispersion 10 times. Do not shake.
- The diluted vaccine should present as an off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.

Gently × 10

- The diluted vials should be marked with the appropriate date and time.
- After dilution, store at 2 °C to 30 °C and use within 6 hours, including any transportation time.
- Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

Record appropriate date and time.
Use within 6 hours after dilution.

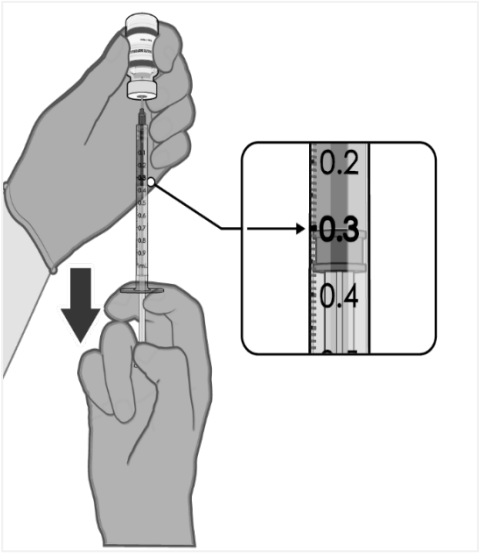
PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (12 YEARS AND OLDER)

- After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty.

Low dead-volume syringes and/or needles should be used in order to extract 6 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 a sixth dose from a single vial.

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Discard any unused vaccine within 6 hours after dilution.



0.3 mL diluted vaccine

Disposal

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

Fuljett ta' tagħrif: Informazzjoni għall-utent

Comirnaty™ 30 mikrogramma/doża

konċentrat għal dispersjoni għall-injezzjoni

Adulti u adolexxenti minn 12-il sena 'l fuq

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' jkollok. 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 ikollok 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

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

Comirnaty 30 mikrogramma/doża konċentrat għal dispersjoni għall-injezzjoni jingħata lil adulti u adolexxenti b'età minn 12-il sena 'l fuq.

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 jagħtik COVID-19.

2 X'għandek tkun taf qabel ma tirċievi Comirnatv

Comirnaty m'għandux jingħata

- ·jekk inti allerġiku 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 tingħata dan il-vaċċin jekk:

- qatt kellek reazzjoni allerġika severa jew problemi bin-nifs wara l-injezzjoni ta' kwalunkwe vaċċin ieħor jew wara li ngħatajt Comirnaty fil-passat.
- qed tħossok nervuż dwar il-proċess tat-tilqim jew jekk xi darba intlift minn sensik wara kwalunkwe injezzjoni b'labra.
- għandek marda severa jew infezzjoni b'deni għoli. Madankollu, tista' tieħu t-tilqima tiegħek jekk ikollok deni ħafif jew infezzjoni ħafifa tal-parti ta' fuq tal-passaġġ tan-nifs bħal riħ.
- għandek problema ta' ħruġ ta' demm, titbenġel malajr jew tuża mediċina biex tipprevjeni emboli tad-demm.
- għandek sistema immuni mdgħajfa, minħabba marda bħal infezzjoni bl-HIV jew mediċina bħal kortikosterojdi li taffettwa s-sistema immuni tiegħek.

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. 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.

Tista' tirċievi t-tielet doża ta' Comirnaty. Anke wara t-tielet doża, l-effikaċja ta' Comirnaty tista' tkun inqas 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 mhux rakkomandat għal tfal b'età ta' inqas minn 12-il sena.

Mediċini oħra u Comirnaty

Għid lit-tabib jew lill-ispiżjar tiegħek jekk qed tuża, użajt dan l-aħħar jew tista' tuża xi mediċini oħra jew jekk riċentement irċevejt xi vaċċin ieħor.

Tqala u treddigħ

Jekk inti tqila jew qed tredda', taħseb li tista' tkun tqila jew qed tippjana li jkollok tarbija, itlob il-parir tat-tabib jew tal-ispiżjar tiegħek qabel tirċievi dan il-vaċċin.

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 ssuq jew tħaddem magni. Stenna sakemm dawn l-effetti jgħaddu qabel ma ssuq jew tħaddem magni.

Comirnaty fih potassium u sodium

Dan il-vaċċin fih anqas minn 1 mmol potassium (39 mg) f'kull doża, jiġifieri essenzjalment 'ħieles mill-potassium'.

Dan il-vaċċin fih anqas minn 1 mmol sodium (23 mg) f'kull doża, jiġifieri essenzjalment 'ħieles mis-sodium'.

3 Kif jingħata Comirnaty

Comirnaty jingħata wara d-dilwizzjoni bħala injezzjoni ta' 0.3 mL ġo muskolu fin-naħa ta' fuq tad-driegħ tiegħek.

Inti ser tirċievi 2 injezzjonijiet.

Huwa rakkomandat li tirċievi t-tieni doża tal-istess vaċċin 3 ġimgħat wara l-ewwel doża biex tlesti l-kors ta' tilqim.

Doża *booster* (it-tielet doża) ta' Comirnaty tista' tingħata mill-inqas 6 xhur wara t-tieni doża f'individwi b'età ta' 18 il sena jew aktar.

Jekk inti immunokompromess(a), tista' tirċievi t-tielet doża ta' Comirnaty mill-inqas 28 jum wara t-tieni doża.

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

- sit tal-injezzjoni: uġigħ, nefħa
- għeja
- uġigħ ta' ras
- uġigħ fil-muskoli
- tkexkix ta' bard
- uġigħ fil-ġogi

- dijarea
- deni

Uħud minn dawn l-effetti sekondarji kienu kemmxejn aktar frekwenti f'adolexxenti b'età minn 12 sa 15-il sena milli fl-adulti.

Effetti sekondarji komuni: jistgħu jaffettwaw sa persuna waħda minn kull 10
- ħmura fis-sit tal-injezzjoni
- dardir
- rimettar

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 jew ħakk
- tħossok dgħajjef jew b'nuqqas ta' enerġija/bi ngħas
- tnaqqis fl-aptit
- 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)

Rappurtar tal-effetti sekondarji
Jekk ikollok 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. Waqt id-9 xhur li fihom idum tajjeb il-prodott, kunjetti mhux miftuħa jistgħu jinħażnu u jiġu ttrasportati f'temperatura ta' -25 °C sa -15 °C għal perjodu wieħed sa ġimagħtejn u wara jistgħu jinħażnu mill-ġdid f'temperatura ta' -90 °C sa -60 °C.

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

Meta jinħażnu ffriżati f'temperatura ta' -90 °C sa -60 °C, pakketti b'195 kunjett tal-vaċċin jistgħu jinħallu mis-silġ f'temperatura ta' 2 °C sa 8 °C għal 3 sigħat jew kunjetti individwali jistgħu jinħallu f'temperatura tal-kamra (sa 30 °C) għal 30 minuta.

Trasferimenti ta' kunjetti ffriżati maħżuna f'temperatura baxxa ħafna (< -60 °C)
- Trejs tal-kunjetti b'għatu magħluq li fihom 195 kunjett imneħħija minn ħażna fil-friża f'temperatura baxxa ħafna (< -60 °C) jistgħu jinżammu f'temperaturi sa 25 °C sa 5 minuti.
- Trejs tal-kunjetti b'għatu miftuħ, jew trejs tal-kunjetti li fihom inqas minn 195 kunjett, imneħħija minn ħażna fil-friża f'temperatura baxxa ħafna (< -60 °C) jistgħu jinżammu f'temperaturi sa 25 °C sa 3 minuti.
- Wara li t-trejs tal-kunjetti jitpoġġew lura f'ħażna fil-friża wara esponiment għal temperatura sa 25 °C, għandhom jibqgħu f'ħażna fil-friża għal mill-inqas sagħtejn qabel ma jkunu jistgħu jerġgħu jitneħħew.

Trasferimenti ta' kunjetti ffriżati maħżuna f'temperatura ta' -25 °C sa -15 °C
- Trejs tal-kunjetti b'għatu magħluq li fihom 195 kunjett imneħħija minn ħażna fil-friża (-25 °C sa -15 °C) jistgħu jinżammu f'temperaturi sa 25 °C sa 3 minuti.
- Trejs tal-kunjetti b'għatu miftuħ, jew trejs tal-kunjetti li fihom inqas minn 195 kunjett, imneħħija minn ħażna fil-friża (- 25 °C sa -15 °C) jistgħu jinżammu f'temperaturi sa 25 °C sa minuta waħda.

Ladarba kunjett jitneħħa mit-trej tal-kunjetti, għandu jinħall mis-silġ għall-użu.

Wara li jinħall mis-silġ, il-vaċċin għandu jiġi dilwit u użat immedjatament. Madankollu, data dwar l-istabbiltà waqt l-użu wriet li ladarba jitneħħa mill-friża, il-vaċċin mhux dilwit jista' jinħażen sa xahar f'temperatura ta' 2 °C sa 8 °C waqt id-9 xhur li fihom idum tajjeb il-prodott. Waqt dan ix-xahar li fih idum tajjeb f'temperatura ta' 2 °C sa 8 °C, sa 12-il siegħa jistgħu jintużaw għat-trasport. Qabel l-użu, il-vaċċin mhux miftuħ jista' jinħażen għal massimu ta' sagħtejn f'temperaturi sa 30 °C

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

Wara d-dilwizzjoni, aħżen u ttrasporta l-vaċċin f'temperatura ta' 2 °C sa 30 °C u użah fi żmien 6 sigħat. Armi kwalunkwe vaċċin mhux użat.

Ladarba jitneħħew mill-friża u jiġu dilwiti, il-kunjetti għandhom jiġu mmarkati bid-data u l-ħin tar-rimi l-ġodda. Ladarba jinħall mis-silġ, il-vaċċin ma jistax jiġi ffriżat mill-ġdid.

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 6 doži ta' 0.3 mL bi 30 mikrogramma 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
  - potassium chloride

– potassium dihydrogen phosphate
– sodium chloride
– disodium phosphate dihydrate
– sucrose
– ilma għall-injezzjonijiet
– sodium hydroxide (għall-aġġustament tal-pH)
– hydrochloric acid (għall-aġġustament tal-pH)

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' 6 dożi f'kunjett trasparenti ta' 2 mL (ħġieġ tat-tip I), b'tapp tal-lastku u għatu tal-plastik vjola li jitneħħa b'daqqa ta' saba' b'siġill tal-aluminju.

Daqs tal-pakkett: 195 kunjett

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

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

Malta
Vivian Corporation Ltd, Tel: +35621 344610

Dan il-fuljett kien rivedut l-aħħar fl-01/2022

Din il-mediċina ngħatat 'approvazzjoni kondizzjonali'. Dan ifisser li għad trid tingħata aktar evidenza dwar din il-mediċina. L-Aġenzija Ewropea għall-Mediċini ser tirrevedi l-informazzjoni l-ġdida dwar din il-mediċina mill-anqas kull sena u ser taġġorna dan il-fuljett kif meħtieġ.

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:

Aġħti Comirnaty ġol-muskoli wara d-dilwizzjoni bħala kors primarju ta' 2 dożi (0.3 mL kull waħda) 3 ġimgħat bogħod minn xulxin. Doża *booster* (it-tielet doża) ta' Comirnaty tista' tingħata mill-inqas 6 xhur wara t-tieni doża f'individwi b'età ta' 18 il sena jew aktar.

It-tielet doża tista' tingħata mill-inqas 28 jum wara t-tieni doża lil individwi li huma immunokompromessi b'mod sever.

Traċċabilità

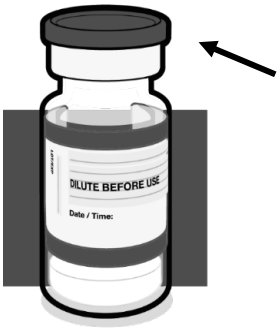
Sabiex tittejjeb it-traċċabilità tal-prodotti mediċinali bijoloġiċi, l-isem u n-numru tal-lott tal-prodott amministrat għandhom jiġu rrekordjati b'mod ċar.

Istruzzjonijiet dwar l-immaniġġar

Comirnaty għandu jiġi ppreparat minn professjonist tal-kura tas-saħħa permezz ta' teknika asettika biex tiġi żgurata l-isterilità tad-dispersjoni ppreparata.

VERIFIKA TAD-DOŻA TA' COMIRNATY 30 MIKROGRAMMA/DOŻA KONĊENTRAT GĦAL DISPERSJONI GĦALL-INJEZZJONI (12-IL SENA JEW AKTAR)

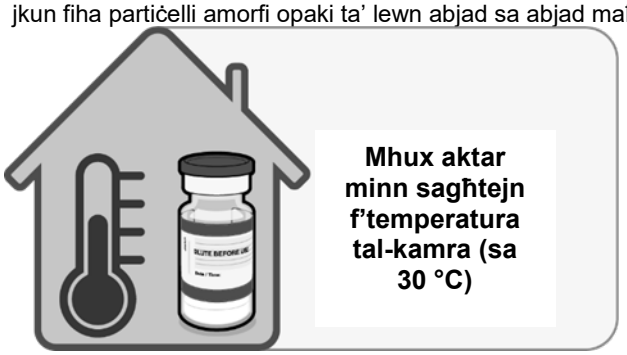
- Ivverifika li l-kunjett għandu għatu tal-plastik vjola.
- Jekk il-kunjett għandu għatu tal-plastik griż, jekk jogħġbok irreferi għas-Sommarju tal-Karatteristiċi tal-Prodott għal Comirnaty 30 mikrogramma/doża dispersjoni għall-injezzjoni.
- Jekk il-kunjett għandu għatu tal-plastik oranġjo, jekk jogħġbok irreferi għas-Sommarju tal-Karatteristiċi tal-Prodott għal Comirnaty 10 mikrogrammi/doża konċentrat għal dispersjoni għall-injezzjoni.



Għatu vjola

KIF TĦOLL MIS-SILĠ QABEL ID-DILWIZZJONI TA' COMIRNATY 30 MIKROGRAMMA/DOŻA KONĊENTRAT GĦAL DISPERSJONI GĦALL-INJEZZJONI (12-IL SENA JEW AKTAR)

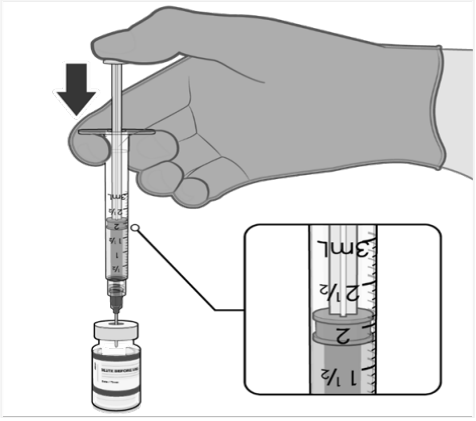
- Il-kunjett b'aktar minn doża waħda jinħażen iffriżat u għandu jinħall mis-silġ qabel ma jiġi dilwit. Kunjetti ffriżati għandhom jiġu ttrasferiti għal ambjent b'temperatura ta' 2 °C sa 8 °C biex jinħallu mis-silġ; pakkett ta' 195 kunjett jista' jieħu 3 sigħat biex jinħall mis-silġ. Inkella, kunjetti ffriżati jistgħu wkoll jinħallu mis-silġ għal 30 minuta f'temperaturi sa 30 °C għal użu immedjat.
- Waqt id-9 xhur li fihom idum tajjeb, il-kunjett mhux miftuħ jista' jinħażen sa xahar f'temperatura ta' 2 °C sa 8 °C. Waqt dan ix-xahar li fih idum tajjeb f'temperatura ta' 2 °C sa 8 °C, sa 12-il siegħa jistgħu jintużaw għat-trasport.
- Ħalli l-kunjett li jkun inħall mis-silġ jilħaq it-temperatura tal-kamra. Qabel l-użu, il-kunjett mhux miftuħ jista' jinħażen għal perjodu sa sagħtejn f'temperaturi sa 30 °C. Kunjetti li nħallu mis-silġ jistgħu jiġu mmaniġġjati f'kondizzjonijiet ta' dawl tal-kamra.
- Aqleb il-kunjett ta' taħt fuq bil-mod 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 maħmu



Mhux aktar minn sagħtejn f'temperatura tal-kamra (sa 30 °C)

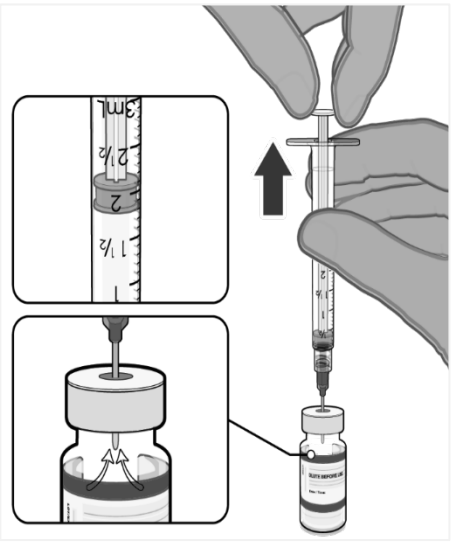
DILWIZZJONI TA' COMIRNATY 30 MIKROGRAMMA/DOŻA KONĊENTRAT GĦAL DISPERSJONI GĦALL-INJEZZJONI (12-IL SENA JEW AKTAR)

- ·It-tilqima li tkun inħallet mis-silġ għandha tiġi dilwita fil-kunjett oriġinali tagħha b'1.8 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.



1.8 mL ta’ injezzjoni ta’ 0.9% sodium chloride

- Ugwalizza l-pressjoni fil-kunjett qabel ma tneħħi l-labra mit-tapp tal-kunjett billi tiġbed 1.8 mL ta’ arja fis-siringa tad-dilwent vojta.



Iġbed il-planġer lura sa 1.8 mL biex tneħħi l-arja mill-kunjett.

- Aqleb id-dispersjoni dilwita ta’ taħt fuq bil-mod għal 10 darbiet. Tħawwadx.
- Il-vaċċin dilwit għandu jidher bħala dispersjoni ta’ lewn abjad maħmuġ mingħajr l-ebda partiċelli viżibbli. Tużax il-vaċċin dilwit jekk ikun hemm frak jew tibdil fil-kulur.

Bil-mod × 10

- 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 6 sigħat, li jinkludu kwalunkwe ħin li fih jiġi ttrasportat.
- Tiffriżax u tħawwadx id-dispersjoni dilwita. Jekk titpoġġa fi friġġ, ħalli id-dispersjoni dilwita tilħaq it-temperatura tal-kamra qabel l-użu.

Irreġistra d-data u l-ħin xierqa. Uża fi żmien 6 sigħat wara d-dilwizzjoni.

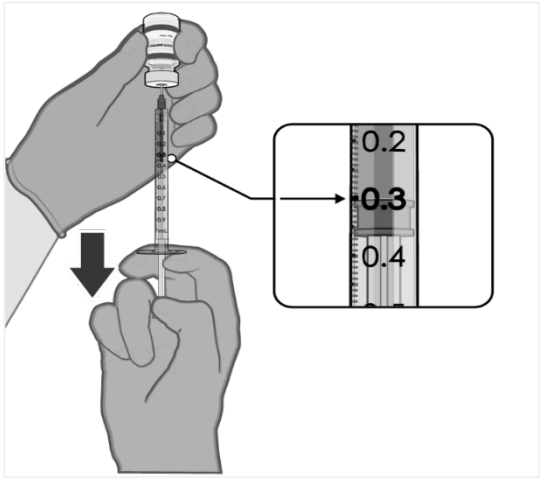
PREPARAZZJONI TA’ DOŻI INDIVIDWALI TA’ 0.3 mL TA’ COMIRNATY 30 MIKROGRAMMA/DOŻA KONĊENTRAT GĦAL DISPERSJONI GĦALL-INJEZZJONI (12-IL SENA JEW AKTAR)

- Wara d-dilwizzjoni, il-kunjett ikun fih 2.25 mL li minnhom jistgħu jinġibdu 6 doži ta’ 0.3 mL.
- Bl-użu ta’ teknika asettika, naddaf it-tapp tal-kunjett b’imselħa antisettika li tintuża darba u tintrema.
- Iġbed 0.3 mL ta’ Comirnaty.

Sabiex jinġibdu 6 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 tinġibed is-sitt doża minn kunjett wieħed.

- Kull doża għandu jkun fiha 0.3 mL ta’ vaċċin.
- Jekk l-ammont ta’ vaċċin li jifdal fil-kunjett ma jistax jipprovdi doża sħiħa ta’ 0.3 mL, armi l-kunjett u kwalunkwe volum żejjed.
- Armi kwalunkwe vaċċin mhux użat fi żmien 6 sigħat wara d-dilwizzjoni.



Vaċċin dilwit ta’ 0.3 mL

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.