Fuljett ta' tagħrif: Informazzjoni għall-utent

BIMERVAX® emulsjoni għall-injezzjoni
Vaċċin kontra l-COVID-19 (rikombinanti, imsaħħaħ)
selvacovatein

▼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-ispizjar 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 BIMERVAX u għalxiex jintuża

BIMERVAX huwa vaċċin li jintuża biex jipprevjeni l-COVID-19 ikkawżat mill-virus tas-SARS-CoV-2.

BIMERVAX jingħata lil individwi ta' età ta' 16-il sena u aktar li preċedentement jkunu rċevew vaċċin tal-mRNA kontra l-COVID-19

Il-vaċċin jistimula lis-sistema immunitarja (id-difiżi naturali tal-ġisem) biex tipproduċi antikorpi speċifiċi li jaħdmu kontra l-virus, filwaqt li jagħtu protezzjoni kontra l-COVID-19. L-ebda wieħed mill-ingredjenti f'dan il-vaċċin ma jista' jikkawża l-COVID-19.

2. X'għandek tkun taf qabel ma tirċievi BIMERVAX

BIMERVAX ma għandux jingħata
- jekk inti allerġiku għal 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 tirċievi BIMERVAX jekk:
- inti qatt kellek reazzjoni allerġika severa jew ta' periklu għall-ħajja wara li rċivejt xi injezzjoni b'vaċċin ieħor
- inti qatt tak ħass ħażin wara kwalunkwe injezzjoni b'labra,
- inti għandek temperatura għolja (aktar minn 38°C) jew infezzjoni severa. Madankollu, inti tista' tieħu t-tilqima tiegħek jekk ikollok ftit deni jew infezzjoni ħafifa fil-pajpijiet tan-nifs bħal riħ (mediċina antikoagulanti),

- inti għandek problemi ta' fsada, titbenġel malajr jew tuża mediċina biex tevita l-emboli tad-demm;
- is-sistema immunitarja tiegħek ma taħdimx kif suppost (immunodefiċjenza) jew inti qed tieħu mediċini li jdgħajfu s-sistema immunitarja (bħal kortikosterojdi b'doża għolja, immunosoppressanti jew mediċini kontra l-kanċer),

Jekk xi waħda minn dawn ta' hawn fuq tapplika għalik (jew jekk ikollok xi dubju), kellem lit-tabib, lill-ispizjar jew lill-infermier tiegħek qabel ma tingħata BIMERVAX.

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

Tfal u adolexxenti
BIMERVAX mhuwiex rakkomandat fi tfal li għandhom inqas minn 16-il sena. Attwalment ma hemm l-ebda informazzjoni disponibbli dwar l-użu ta' BIMERVAX fi tfal iżgħar minn 16-il sena.

Mediċini oħra u BIMERVAX
Għid lit-tabib, lill-ispiżjar, jew lill-infermier tiegħek jekk qed tieħu, ħadt dan l-aħħar jew tista' tieħu xi mediċini jew vaċċini oħra.

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, tal-ispiżjar, jew tal-infermier tiegħek qabel tirċievi dan il-vaċċin.

Sewqan u tħaddim ta' magni
Xi wħud mill-effetti sekondarji ta' BIMERVAX elemkati fis-sezzjoni 4 (Effetti sekondarji possibbli) jistgħu jnaqqsu b'mod temporanju l-ħila tiegħek biex issuq u tħaddem magni. Stenna sakemm jitlaq kwalunkwe effett tal-vaċċin qabel ma ssuq jew tħaddem magni.

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

Dan il-vaċċin fih anqas minn 1 mmol potassium (39 mg) f'kull doża ta' 0.5 ml, jiġifieri essenzjalment "ħieles mill-potassium".

Dan il-vaċċin fih 1.18 mg ta' polysorbate 80 f'kull doża. Polysorbates jistgħu jikkawżaw reazzjonijiet allerġiċi. Għid lit-tabib tiegħek jekk għandek xi allerġiji magħrufa.

3. Kif jingħata BIMERVAX

Individwi ta' età ta' 16-il sena u aktar
BIMERVAX se jingħatalek bħala injezzjoni ta' 0.5 ml f'muskolu tal-parti ta' fuq tad-driegħ tiegħek.

Huwa rakkomandat li tirċievi BIMERVAX bħala doża waħda mill-inqas 6 xhur wara serje ta' tilqim preċedenti b'vaċċin tal-mRNA kontra l-COVID-19 jew wara doża booster preċedenti ta' BIMERVAX.

Wara l-injezzjoni, it-tabib, l-ispiżjar jew l-infermier tiegħek se jħarsuk għal madwar 15-il minuta biex jimmonitorjaw għal sinjali ta' reazzjoni allerġika.

Jekk għandek aktar mistoqsijiet dwar l-użu ta' BIMERVAX, staqsi lit-tabib, lill-ispiżjar jew lill-infermier tiegħek.

Individwi immunokompromessi

Jekk is-sistema immunitarja tiegħek ma taħdimx kif suppost, jistgħu jingħataw dożi addizzjonali f'konformità mar-rakkomandazzjonijiet uffiċjali.

4. Effetti sekondarji possibbli

Bħal kull mediċina oħra, dan il-vaċċin jista' tikkawża effetti sekondarji, għalkemm ma jidhrux f'kulħadd.

Il-biċċa l-kbira tal-effetti sekondarji jseħħu fi żmien 3 ijiem wara li tirċievi l-vaċċin u jgħaddu fi żmien ftit jiem minn meta jidhru. Jekk is-sintomi jippersistu, ikkuntattja lit-tabib, lill-ispiżjar jew lill-infermier tiegħek.

Ikseb attenzjoni medika urġenti jekk ikollok sintomi ta' reazzjoni allerġika severa ftit wara t-tilqima. Sintomi bħal dawn jistgħu jinkludu:
- tħossok li se jagħtik ħass ħażin jew tistordi
- tibdil fit-taħbit ta' qalbek
- qtugħ ta' nifs
- tħarħir
- nefħa f'xuftejk, f'wiċċek jew fi griżmejk
- nefħiet li jġegħluk tħokk taħt il-ġilda (ħorriqija) jew raxx
- tħossok imqalla (dardir) jew rimettar
- uġigħ fl-istonku

L-effetti sekondarji li ġejjin jistgħu jseħħu b'BIMERVAX:

Komuni ħafna (jistgħu jaffettwaw aktar minn persuna 1 minn kull 10)
- uġigħ ta' ras
- uġigħ fejn tingħata l-injezzjoni
- tħossok għajjien ħafna (għeja)
- uġigħ fil-muskoli

Komuni(jistgħu jaffettwaw sa persuna 1 minn kull 10)
- ħmura, nefħa jew sensittività fejn tingħata l-injezzjoni
- tħossok ma tiflaħx (dardir) jew tkun imdardar (tirremetti)
- dijarea
- deni
- limfonodi mkabbra
- uġigħ taħt l-abt

Mhux komuni (jistgħu jaffettwaw sa persuna 1 minn kull 100)
- sirdat jew tħoss li se jaqbdek id-deni
- sturdament
- ħakk fejn tkun ingħatat l-injezzjoni
- uġigħ fil-ġogi
- tħossok dgħajjef jew nuqqas ta' enerġija
- tħossok bi ngħas
- ħakk fil-ġilda
- tħossok ma tiflaħx b'mod ġenerali

Rari (jistgħu jaffettwaw sa persuna 1 minn kull 1000)
- għaraq kiesaħ
- tħoss affarijiet mhux tas-soltu fil-ġilda, bħal tingiż jew tħoss bħal insetti jiġru (paresteżija)
- nuqqas ta' sens tas-sensittività, speċjalment fil-ġilda (ipoesteżija)
- uġigħ addominali

- uġigħ meta tibla'
- reazzjonijiet allerġiċi bħal ħorriqija, raxx jew ħakk
- tbenġil fejn tingħata l-injezzjoni
- sensittività eċċessiva fejn tkun ingħatat l-injezzjoni

Mhux magħruf (ma tistax tittieħed stima mid-data disponibbli, ibbażata fuq każ wieħed waqt provi kliniċi)
- infjammazzjoni tar-rita ta' barra tal-qalb (perikardite), li tista' tirriżulta fi qtugħ ta' nifs, palpitazzjonijiet jew uġigħ fis-sider

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
ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal
u tinkludi n-numru tal-lott/Lott jekk disponibbli. Billi tirrapporta l-effetti sekondarji tista' tgħin biex tiġi pprovduta aktar informazzjoni dwar is-sigurtà ta' dan il-vaċċin.

5. Kif taħżen BIMERVAX

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

It-tabib, l-ispiżjar jew l-infermier tiegħek huma responsabbli għall-ħażna ta' dan il-vaċċin u għar-rimi b'mod korrett ta' kwalunkwe prodott li ma jkunx intuża. It-tagħrif li jmiss dwar il-ħażna, l-iskadenza, l-użu u l-immaniġġjar kif ukoll ir-rimi qed jingħata biss għall-professjonisti tal-kura tas-saħħa biss.

Tużax dan il-vaċċin wara d-data ta' meta jiskadi li tidher fuq it-tikketta wara JIS. Id-data ta' meta tiskadi tirreferi għall-aħħar ġurnata ta' dak ix-xahar.

Aħżen fi friġġ (2°C – 8°C). Tagħmlux fil-friża. Żomm il-kunjetti fil-kartuna ta' barra sabiex tilqa' mid-dawl.
Wara li l-kunjett b'ħafna dożi jittaqqab l-ewwel darba, aħżen f'temperatura ta' 2°C – 8°C, uża fi żmien 6 siegħat.

L-informazzjoni dwar l-immaniġġar hija deskritta fis-sezzjoni maħsuba għall-professjonisti tal-kura tas-saħħa fi tmiem il-fuljett ta' tagħrif.

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.

6. Kontenut tal-pakkett u informazzjoni oħra

X'fih BIMERVAX

- Doża waħda (0.5 ml) fiha 40 mikrogramma ta' selvacovatein imsaħħaħ b'SQBA.

- Selvacovatein huwa eterodimer tal-fużjoni tal-RBD tal-proteina spika (S) rikombinanti tal-virus tas-SARS-CoV-2 *il-varjazzjonijiet B.1.351-B.1.1.7) prodott permezz ta' teknoloġija tad-DNA rikombinanti.

- SQBA huwa inkluż f'dan il-vaċċin bħala aġġuvant biex jaċċellera u jtejjebl-effetti protettivi tal-vaċċin. Għal kull doża ta' 0.5 ml, SQBA fih: squalene (9.75 mg), polysorbate 80 (1.18 mg), sorbitan trioleate (1.18 mg), sodium citrate (0.66 mg), citric acid (0.04 mg) u ilma għall-injezzjoniijiet.

- Is-sustanzi mhux attivi (eċċipjenti) l-oħra huma: disodium phosphate dodecahydrate, potassium dihydrogen phosphate, sodium chloride, potassium chloride u ilma għall-injezzjonijiet. BIMERVAX fih potassium, sodium u polysorbate (ara sezzjoni 2).

Kif jidher BIMERVAXu l-kontenut tal-pakkett

Il-vaċċin huwa emulsjoni omoġenja bajda għall-injezzjoni.

Kunjett b'ħafna dożi

5 ml ta' emulsjoni hija pprovduta f'kunjett b'tapp tal-gomma u b'għatu tal-plastik tat-tip flip off.

Kull kunjett b'ħafna dożi fih 10 dożi ta' 0.5 ml.

Daqs tal-pakkett: 10 kunjetti b'ħafna dożi.

Kunjett b'doża waħda

0.5 ml ta' emulsjoni hija pprovduta f'kunjett b'tapp tal-gomma u b'għatu tal-plastik tat-tip flip off.

Kull kunjett b'doża waħda fih doża waħda ta' 0.5 ml.

Daqsijiet tal-pakkett: 5, 10 jew 20 kunjett b'doża waħda.

Jista' jkun li mhux id-daqsijiet tal-pakkett kollha jkunu fis-suq.

Detentur tal-Awtorizzazzjoni għat-Tqegħid fis-Suq

Hipra Human Health, S.L.U.
Avda. la Selva, 135
17170 Amer (Girona)
SPANJA

Manifattur

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPANJA

Dan il-fuljett kien rivedut l-aħħar f' 04/2025

Sorsi oħra ta' informazzjoni

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

Skennja l-kodiċi b'apparat mobbli biex tikseb il-fuljett ta' tagħrif f'lingwi differenti.

Jew żur il-URL: www.hipracovidvaccine.com

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 BIMERVAX ġol-muskoli, preferibbilment fil-muskolu deltojde tal-parti ta' fuq tad-driegħ.

Traċċabilità

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

Istruzzjonijiet dwar l-immaniġġjar u l-għoti

Tużax dan il-vaċċin wara d-data ta' meta jiskadi li tidher fuq it-tikketta wara JIS. Id-data ta' meta jiskadi tirreferi għall-aħħar ġurnata ta' dak ix-xahar.

Dan il-vaċċin għandu jiġi mmaniġġat minn professjonist fil-kura tas-saħħa bl-użu ta' tekniki asettiċi sabiex tiġi żgurata l-isterilità ta' kull doża.

Preparazzjoni għall-użu
- Il-vaċċin jiġi lest biex jintuża.
- Vaċċin mhux miftuħ għandu jinħażen f'temperatura ta' 2°C sa 8°C u jinżamm fil-kaxxa ta' barra sabiex tilqa' mid-dawl.
- Immedjatament qabel l-użu, oħroġ il-kunjett tal-vaċċin mill-kartuna fil-friġġ.
- Wara li l-kunjett b'ħafna dożi jittaqqab l-ewwel darba, niżżel id-data u l-ħin tar-rimi (6 siegħat wara li jittaqqab l-ewwel darba) fuq iż-żona magħżula tat-tikketta tal-kunjett

Spezzjona l-kunjett
- Dawwar il-kunjett bil-mod qabel u bejn kull ġbid tad-doża għall-kunjett b'ħafna dożi. Tħawdux.
- Kull kunjett fih emulsjoni bajda u omoġenja.
- Spezzjona viżwalment ilvaċċin għal frak u/jew telf tal-kulur qabel l-għoti. Tagħtix il-vaċċin jekk ikun hemm xi waħda minn dawn.

Agħti l-vaċċin
- Mili żejjed huwa inkluż f'kull kunjett biex jiġi żgurat li jistgħu jiġu estratti massimu ta' għaxar (10) dożi (kunjett b'ħafna dożi) jew doża waħda (kunjett b'doża waħda) ta' 0.5 ml kull waħda.Armi kwalunkwe vaċċin li jkun fadal fil-kunjett b'doża waħda jew fil-kunjett b'ħafna dożi wara li jkunu ġew estratti 10 dożi.
- Kull doża ta' 0.5 ml tingibed f'labra sterili u f'siringa sterili biex tingħata permezz ta' injezzjoni ġol-muskoli, preferibbilment fil-muskolu deltojde tal-parti ta' fuq tad-driegħ.
- Ladarba l-vaċċin jimtela fis-siringa, dan ikun stabbli sa mill-inqas 6 siegħat jew f'kundizzjonijiet ta' tkessiħ jew f'temperatura ambjentali (< 25 ºC).
- Tħallatx il-vaċċin fl-istess siringa ma' kwalunkwe vaċċin ieħor jew prodotti mediċinali oħra.
- Tiġborx vaċċin żejjed minn bosta kunjetti.

Armi

- Wara li l-kunjett b'ħafna dożi jittaqqab għall-ewwel darba, aħżen il-kunjett b'ħafna dożi, miftuħf'temperatura ta' 2 ºC sa 8 ºC sa massimu ta' 6 sigħat. Armi l-vaċċin jekk ma jintużax fi żmien 6 siegħat wara li l-kunjett b'ħafna dożi jittaqqab għall-ewwel darba.
- Armi kwalunkwe fdal tal-vaċċin fil-kunjett b'doża waħda jew fil-kunjett b'ħafna dożi wara li jkunu nġibdu 10 dożi.

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.

Package leaflet: Information for the user

BIMERVAX® emulsion for injection
COVID-19 vaccine (recombinant, adjuvanted)
selvacovatein

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

Read all of this leaflet carefully before you recieve 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 BIMERVAX is and what it is used for

BIMERVAX is a vaccine used to prevent COVID-19 caused by the SARS-CoV-2 virus.

BIMERVAX is given to individuals 16 years of age and older who have previously received a mRNA COVID-19 vaccine.

The vaccine stimulates the immune system (the body's natural defences) to produce specific antibodies that work against the virus, giving protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

2. What you need to know before you receive BIMERVAX

BIMERVAX 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 receiving BIMERVAX if:
- you have ever had a severe or life-threatening allergic reaction after receiving any other vaccine injection;
- you have ever fainted following any needle injection;
- you have a high temperature (over 38 °C) or severe infection. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold;
- you have bleeding problems, you bruise easily or you use a medicine to prevent blood clots (anticoagulant medicine);

- your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants, or cancer medicines).

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist, or nurse before you are given BIMERVAX.

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

Children and adolescents
BIMERVAX is not recommended for children aged below 16 years. Currently, there is no information available on the use of BIMERVAX in children younger than 16 years of age.

Other medicines and BIMERVAX
Tell your doctor, pharmacist, or nurse if you are taking, have recently taken, or might take any other medicines or vaccines.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist, or nurse for advice before you receive this vaccine.

Driving and using machines
Some of the side effects of BIMERVAX listed in section 4 (Possible side effects) may temporarily reduce your ability to drive and use machines. Wait until any effects of the vaccine have worn off before you drive or use machines.

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

This vaccine contains less than 1 mmol potassium (39mg) per 0.5 mL dose, that is to say, essentially 'potassium-free'.

This vaccine contains 1.18 mg of polysorbate 80 in each dose. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How BIMERVAX is given

Individuals 16 years of age and older
BIMERVAX will be given to you as 0.5 mL injection into a muscle of your upper arm.

It is recommended that you receive BIMERVAX as a single dose at least 6 months after a previous vaccination series with mRNA COVID-19 vaccine or after a previous BIMERVAX booster dose.

After the injection, your doctor, pharmacist or nurse will watch over you for around 15 minutes to monitor for signs of an allergic reaction.

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

Immunocompromised individuals
If your immune system does not work properly additional doses may be administered in line with official recommendations.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Most of the side effects occur within 3 days of getting the vaccine and go away within a few days of appearing. If symptoms persist, contact your doctor, pharmacist or nurse.

Get urgent medical attention if you get symptoms of a severe allergic reaction shortly after vaccination. Such symptoms may include:
- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat
- itchy swelling under the skin (hives) or rash
- feeling sick (nausea) or vomiting
- stomach pain

The following side effects may occur with BIMERVAX:

Very common (may affect more than 1 in 10 people)
- headache
- pain where the injection is given
- feeling very tired (fatigue)
- muscle pain

Common (may affect up to 1 in 10 people)
- redness, swelling or tenderness where the injection is given
- feeling sick (nausea) or getting sick (vomiting)
- diarrhoea
- fever
- enlarged lymph nodes
- axillary pain

Uncommon (may affect up to 1 in 100 people):
- chills or feeling feverish
- dizziness
- itching where the injection is given
- joint pain
- feeling weak or lack of energy
- feeling sleepy
- itchy skin
- generally feeling unwell

Rare (may affect up to 1 in 1 000 people):
- cold sweating
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling of sensitivity, especially in the skin (hypoaesthesia)
- abdominal pain
- pain when swallowing
- allergic reactions such as hives, rash or itching
- bruise where the injection is given
- hypersensitivity where the injection is given

Not known (cannot be estimated from available data, based on a single case during clinical trials):
- inflammation of the lining outside the heart (pericarditis), which can result in breathless, palpitations or chest pain

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 vaccine.

5. How to store BIMERVAX

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

Your doctor, pharmacist, or nurse is responsible for storing this vaccine and disposing of any unused product correctly. The following information about storage, expiry, use and handling as well as disposal is intended for healthcare professionals.

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

Store in a refrigerator (2 °C – 8 °C). Do not freeze. Keep vials in outer carton in order to protect from light.
After first puncture of a multidose vial, store at 2 °C – 8 °C, use within 6 hours.

Information on handling are described in the section intended for healthcare professionals at the end of the package leaflet.

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

6. Contents of the pack and other information

What BIMERVAX contains

- One dose (0.5 mL) contains 40 micrograms of selvacovatein adjuvanted with SQBA.

- Selvacovatein is SARS-CoV-2 virus recombinant spike (S) protein RBD fusion heterodimer B.1.351 and B.1.1.7 strains) produced by recombinant DNA technology.

- SQBA is included in this vaccine as an adjuvant to accelerate and improve the protective effects of the vaccine. SQBA contains per 0.5 mL dose: squalene (9.75 mg), polysorbate 80 (1.18 mg), sorbitan trioleate (1.18 mg), sodium citrate (0.66 mg), citric acid (0.04 mg) and water for injections.

- The other ingredients (excipients) are: disodium phosphate dodecahydrate, potassium dihydrogen phosphate, sodium chloride, potassium chloride and water for injections. BIMERVAX contains potassium, sodium and polysorbate (see section 2).

What BIMERVAX looks like and contents of the pack

The vaccine is a white homogeneous emulsion for injection.

Multidose vial

5 mL of emulsion is provided in a vial with a rubber stopper and a plastic flip-off top.

Each multidose vial contains 10 doses of 0.5 mL.

Pack size: 10 multidose vials.

Single dose vial

0.5 mL of emulsion is provided in a vial with a rubber stopper and a plastic flip-off top.

Each single dose vial contains 1 dose of 0.5 mL

Pack sizes: 5, 10 or 20 single dose vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Hipra Human Health, S.L.U.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

Manufacturer

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

This leaflet was last revised in 04/2025

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
https://www.ema.europa.eu

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

Or visit the URL: www.hipracovidvaccine.com

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

The following information is intended for healthcare professionals only:

Administer BIMERVAX intramuscularly, preferably into the deltoid muscle of the upper arm.

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 and administration

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

This vaccine should be handled by a healthcare professional using aseptic techniques to ensure the sterility of each dose.

Preparation for use

- The vaccine comes ready to use.
- Unopened vaccine should be stored at 2 °C to 8 °C and kept within the outer carton to protect from light.
- Immediately prior to use, remove the vaccine vial from the outer carton.
- After first puncture of the multidose vial, record the discard date and time (6 hours after first puncture) on the designated area of the vial label.

Inspect the vial

- Gently swirl the vial before the dose withdrawal and also in between each dose withdrawal for the multidose vial. Do not shake.
- Each vial contains a white and homogeneous emulsion.
- Visually inspect the vaccine for particulate matter and/or discolouration prior to administration. Do not administer the vaccine if any of these are present.

Administer the vaccine:

- An overfill is included in each vial to ensure that a maximum of ten (10) doses (multidose vial) or one dose (single dose vial) of 0.5 mL each can be extracted. Discard any remaining vaccine in single dose vial or in the multidose vial after 10 doses have been extracted.
- Each 0.5 mL dose is withdrawn into a sterile needle and sterile syringe to be administered by intramuscular injection, preferably in the deltoid muscle of the upper arm.
- Once the vaccine is loaded in the syringe, it is stable up to at least 6 hours either under refrigerated conditions or at room temperature (< 25 ºC).
- Do not mix the vaccine in the same syringe with any other vaccines or medicinal products.
- Do not pool excess vaccine from multiple vials.

Discard

- After first puncture the multidose vial, store the opened multidose vial at 2ºC to 8ºC for up to 6 hours. Discard the vaccine if not used within 6 hours after first puncture of the multidose vial.
- Discard any remaining vaccine in single dose vial or in the multidose vial after 10 doses have been extracted.

Disposal:

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

Fuljett ta' tagħrif: Informazzjoni għall-utent

BIMERVAX® XBB.1.16 emulsjoni għall-injezzjoni
Vaċċin kontra l-COVID-19 (rikombinanti, imsaħħaħ)
damlecovatein

▼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-ispizjar 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 BIMERVAX XBB.1.16 u għalxiex jintuża

BIMERVAX XBB.1.16 huwa vaċċin li jintuża biex jipprevjeni l-COVID-19 ikkawżat mill-virus tas-SARS-CoV-2.

BIMERVAX XBB.1.16 jingħata lil individwi ta' età ta' 16-il sena u aktar.

Il-vaċċin jistimula lis-sistema immunitarja (id-difiżi naturali tal-ġisem) biex tipproduċi antikorpi speċifiċi li jaħdmu kontra l-virus, filwaqt li jagħtu protezzjoni kontra l-COVID-19. L-ebda wieħed mill-ingredjenti f'dan il-vaċċin ma jista' jikkawża l-COVID-19.

2. X'għandek tkun taf qabel ma tirċievi BIMERVAX XBB.1.16

BIMERVAX XBB.1.16 ma għandux jingħata
- jekk inti allerġiku għal 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 tirċievi BIMERVAX XBB.1.16 jekk:
- inti qatt kellek reazzjoni allerġika severa jew ta' periklu għall-ħajja wara li rċivejt xi injezzjoni b'vaċċin ieħor
- inti qatt tak ħass ħażin wara kwalunkwe injezzjoni b'labra,
- inti għandek temperatura għolja (aktar minn 38°C) jew infezzjoni severa. Madankollu, inti tista' tieħu t-tilqima tiegħek jekk ikollok ftit deni jew infezzjoni ħafifa fil-pajpijiet tan-nifs bħal riħ (mediċina antikoagulanti),

- inti għandek problemi ta' fsada, titbenġel malajr jew tuża mediċina biex tevita l-emboli tad-demm;
- is-sistema immunitarja tiegħek ma taħdimx kif suppost (immunodefiċjenza) jew inti qed tieħu mediċini li jdgħajfu s-sistema immunitarja (bħal kortikosterojdi b'doża għolja, immunosoppressanti jew mediċini kontra l-kanċer).

Jekk xi waħda minn dawn ta' hawn fuq tapplika għalik (jew jekk ikollok xi dubju), kellem lit-tabib, lill-ispizjar jew lill-infermier tiegħek qabel ma tingħata BIMERVAX XBB.1.16.

Bħal kull vaċċin ieħor, BIMERVAX XBB.1.16 jista' ma jipproteġix b'mod sħiħ lil dawk kollha li jirċevuh, u mhux magħruf kemm inti ser iddum protett.

Tfal u adolexxenti
BIMERVAX XBB.1.16 mhuwiex rakkomandat fi tfal li għandhom inqas minn 16-il sena. Attwalment ma hemm l-ebda informazzjoni disponibbli dwar l-użu ta' BIMERVAX XBB.1.16 fi tfal iżgħar minn 16-il sena.

Mediċini oħra u BIMERVAX XBB.1.16
Għid lit-tabib, lill-ispiżjar, jew lill-infermier tiegħek jekk qed tieħu, ħadt dan l-aħħar jew tista' tieħu xi mediċini jew vaċċini oħra.

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, tal-ispiżjar, jew tal-infermier tiegħek qabel tirċievi dan il-vaċċin.

Sewqan u tħaddim ta' magni
Xi wħud mill-effetti sekondarji ta' BIMERVAX XBB.1.16 elemkati fis-sezzjoni 4 (Effetti sekondarji possibbli) jistgħu jnaqqsu b'mod temporanju l-ħila tiegħek biex issuq u tħaddem magni. Stenna sakemm jitlaq kwalunkwe effett tal-vaċċin qabel ma ssuq jew tħaddem magni.

BIMERVAX XBB.1.16 odium, potassium u polysorbate
Dan il-vaċċin fih anqas minn 1 mmol sodium (23 mg) f'kull doża, jiġifieri essenzjalment "ħieles mis-sodium".

Dan il-vaċċin fih anqas minn 1 mmol potassium (39 milligramma) f'kull doża ta' 0.5 ml, jiġifieri essenzjalment "ħieles mill-potassium".

Dan il-vaċċin fih 1.18 mg ta' polysorbate 80 f'kull doża. Polysorbates jistgħu jikkawżaw reazzjonijiet allerġiċi. Għid lit-tabib tiegħek jekk għandek xi allerġiji magħrufa.

3. Kif jingħata BIMERVAX XBB.1.16

Individwi ta' età ta' 16-il sena u aktar
BIMERVAX XBB.1.16 se jingħatalek bħala injezzjoni ta' 0.5 ml f'muskolu tal-parti ta' fuq tad-driegħ tiegħek.

Huwa rrakkomandat li tirċievi BIMERVAX XBB.1.16 bħala doża waħda mill-inqas 6 xhur wara doża preċedenti ta' vaċċin kontra l-COVID-19.

Wara l-injezzjoni, it-tabib, l-ispiżjar jew l-infermier tiegħek se jħarsuk għal madwar 15-il minuta biex jimmonitorjaw għal sinjali ta' reazzjoni allerġika.

Jekk għandek aktar mistoqsijiet dwar l-użu ta' BIMERVAX XBB.1.16, staqsi lit-tabib, lill-ispiżjar jew lill-infermier tiegħek.

Individwi immunokompromessi

Jekk is-sistema immunitarja tiegħek ma taħdimx kif suppost, jistgħu jingħataw dożi addizzjonali f'konformità mar-rakkomandazzjonijiet uffiċjali.

4. Effetti sekondarji possibbli

Bħal kull mediċina oħra, dan il-vaċċin jista' tikkawża effetti sekondarji, għalkemm ma jidhrux f'kulħadd.

Il-biċċa l-kbira tal-effetti sekondarji jseħħu fi żmien 3 ijiem wara li tirċievi l-vaċċin u jgħaddu fi żmien ftit jiem minn meta jidhru. Jekk is-sintomi jippersistu, ikkuntattja lit-tabib, lill-ispiżjar jew lill-infermier tiegħek.

Ikseb attenzjoni medika urġenti jekk ikollok sintomi ta' reazzjoni allerġika severa ftit wara t-tilqima. Sintomi bħal dawn jistgħu jinkludu:
- tħossok li se jagħtik ħass ħażin jew tistordi
- tibdil fit-taħbit ta' qalbek
- qtugħ ta' nifs
- tħarħir
- nefħa f'xuftejk, f'wiċċek jew fi griżmejk
- nefħiet li jġegħluk tħokk taħt il-ġilda (ħorriqija) jew raxx
- tħossok imqalla (dardir) jew rimettar
- uġigħ fl-istonku

L-effetti sekondarji li ġejjin jistgħu jseħħu b'BIMERVAX XBB.1.16:

Komuni ħafna (jistgħu jaffettwaw aktar minn persuna 1 minn kull 10)
- uġigħ ta' ras
- uġigħ fejn tingħata l-injezzjoni
- tħossok għajjien ħafna (għeja)
- uġigħ fil-muskoli

Komuni (jistgħu jaffettwaw sa persuna 1 minn kull 10)
- ħmura, nefħa jew sensittività fejn tingħata l-injezzjoni
- tħossok ma tiflaħx (dardir) jew tkun imdardar (tirremetti)
- dijarea
- deni
- limfonodi mkabbra
- uġigħ taħt l-abt

Mhux komuni (jistgħu jaffettwaw sa persuna 1 minn kull 100)
- sirdat jew tħoss li se jaqbdek id-deni
- sturdament
- ħakk fejn tkun ingħatat l-injezzjoni
- uġigħ fil-ġogi
- tħossok dgħajjef jew nuqqas ta' enerġija
- tħossok bi ngħas
- ħakk fil-ġilda
- tħossok ma tiflaħx b'mod ġenerali

Rari (jistgħu jaffettwaw sa persuna 1 minn kull 1000)
- għaraq kiesaħ
- tħoss affarijiet mhux tas-soltu fil-ġilda, bħal tingiż jew tħoss bħal insetti jiġru (paresteżija)
- nuqqas ta' sens tas-sensittività, speċjalment fil-ġilda (ipoesteżija)
- uġigħ addominali

- uġigħ meta tibla'
- reazzjonijiet allerġiċi bħal ħorriqija, raxx jew ħakk
- tbenġil fejn tingħata l-injezzjoni
- sensittività eċċessiva fejn tkun ingħatat l-injezzjoni

Mhux magħruf (ma tistax tittieħed stima mid-data disponibbli, ibbażata fuq każ wieħed waqt provi kliniċi)
- infjammazzjoni tar-rita ta' barra tal-qalb (perikardite), li tista' tirriżulta fi qtugħ ta' nifs, palpitazzjonijiet jew uġigħ fis-sider

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-
ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal
u tinkludi n-numru tal-lott/Lott jekk disponibbli. Billi tirrapporta l-effetti sekondarji tista' tgħin biex tiġi pprovduta aktar informazzjoni dwar is-sigurtà ta' dan il-vaċċin.

5. Kif taħżen BIMERVAX XBB.1.16

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

It-tabib, l-ispiżjar jew l-infermier tiegħek huma responsabbli għall-ħażna ta' dan il-vaċċin u għar-rimi b'mod korrett ta' kwalunkwe prodott li ma jkunx intuża. It-tagħrif li jmiss dwar il-ħażna, l-iskadenza, l-użu u l-immaniġġjar kif ukoll ir-rimi qed jingħata biss għall-professjonisti tal-kura tas-saħħa biss.

Tużax dan il-vaċċin wara d-data ta' meta jiskadi li tidher fuq it-tikketta wara JIS. Id-data ta' meta tiskadi tirreferi għall-aħħar ġurnata ta' dak ix-xahar.

Aħżen fi friġġ (2°C – 8°C). Tagħmlux fil-friża. Żomm il-kunjetti fil-kartuna ta' barra sabiex tilqa' mid-dawl.

L-informazzjoni dwar l-immaniġġar hija deskritta fis-sezzjoni maħsuba għall-professjonisti tal-kura tas-saħħa fi tmiem il-fuljett ta' tagħrif.

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.

6. Kontenut tal-pakkett u informazzjoni oħra

X'fih BIMERVAX XBB.1.16

- Doża waħda (0.5 ml) fiha 40 mikrogramma ta' damlecovatein imsaħħaħ b'SQBA.

- Damlecovatein huwa omodimeru tal-fużjoni tal-RBD tal-proteina spika (S) rikombinanti tal-virus tas-SARS-CoV-2 il-varjazzjonijiet (Omicron XBB.1.16 - XBB.1.16) prodott permezz ta' teknoloġija tad-DNA rikombinanti.

- SQBA huwa inkluż f'dan il-vaċċin bħala aġġuvant biex jaċċellera u jtejjebl-effetti protettivi tal-vaċċin. Għal kull doża ta' 0.5 ml, SQBA fih: squalene (9.75 mg), polysorbate 80 (1.18 mg), sorbitan trioleate (1.18 mg), sodium citrate (0.66 mg), citric acid (0.04 mg) u ilma għall-injezzjoniijiet.

- Is-sustanzi mhux attivi (eċċipjenti) l-oħra huma: disodium phosphate dodecahydrate, potassium dihydrogen phosphate, sodium chloride, potassium chloride u ilma għall-injezzjonijiet. BIMERVAX XBB.1.16 fih potassium, sodium u polysorbate (ara sezzjoni 2).

Kif jidher BIMERVAX XBB.1.16 u l-kontenut tal-pakkett

Il-vaċċin huwa emulsjoni omoġenja bajda għall-injezzjoni.

0.5 ml ta' emulsjoni hija pprovduta f'kunjett b'tapp tal-gomma u b'għatu tal-plastik tat-tip flip off.

Kull kunjett b'doża waħda fih doża waħda ta' 0.5 ml.

Daqsijiet tal-pakkett: 5, 10 jew 20 kunjett b'doża waħda.

Detentur tal-Awtorizzazzjoni għat-Tqegħid fis-Suq

Hipra Human Health, S.L.U.
Avda. la Selva, 135
17170 Amer (Girona)
SPANJA

Manifattur

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPANJA

Dan il-fuljett kien rivedut l-aħħar f' 04/2025

Sorsi oħra ta' informazzjoni

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

Skennja l-kodiċi b'apparat mobbli biex tikseb il-fuljett ta' tagħrif f'lingwi differenti.

Jew żur il-URL: www.hipracovidvaccine.com

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 BIMERVAX XBB.1.16 ġol-muskoli, preferibbilment fil-muskolu deltojde tal-parti ta' fuq tad-driegħ.

Traċċabilità

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

Istruzzjonijiet dwar l-immaniġġjar u l-għoti

Tużax dan il-vaċċin wara d-data ta' meta jiskadi li tidher fuq it-tikketta wara JIS. Id-data ta' meta jiskadi tirreferi għall-aħħar ġurnata ta' dak ix-xahar.

Dan il-vaċċin għandu jiġi mmaniġġat minn professjonist fil-kura tas-saħħa bl-użu ta' tekniki asettiċi sabiex tiġi żgurata l-isterilità ta' kull doża.

Preparazzjoni għall-użu
- Il-vaċċin jiġi lest biex jintuża.
- Vaċċin mhux miftuħ għandu jinħażen f'temperatura ta' 2°C sa 8°C u jinżamm fil-kaxxa ta' barra sabiex tilqa' mid-dawl.
- Immedjatament qabel l-użu, oħroġ il-kunjett tal-vaċċin mill-kartuna fil-friġġ.

Spezzjona l-kunjett
- Dawwar il-kunjett bil-mod qabel ma tiġbed id-doża. Tħawdux.
- Kull kunjett fih emulsjoni bajda u omoġenja.
- Spezzjona viżwalment ilvaċċin għal frak u/jew telf tal-kulur qabel l-għoti. Tagħtix il-vaċċin jekk ikun hemm xi waħda minn dawn.

Agħti l-vaċċin
- F'kull kunjett hija inkluża żieda fil-volum biex jiġi żgurat li tista' tiġi estratta kull doża ta' 0.5 mL. Armi kwalunkwe vaċċin li jifdal fil-kunjett.
- Doża waħda ta' 0.5 mL tinġibed f'labra sterili u f'siringa sterili biex tingħata permezz ta' injezzjoni ġol-muskoli, preferibbilment fil-muskolu deltojde tal-parti ta' fuq tad-driegħ.
- Tħallatx il-vaċċin fl-istess siringa ma' kwalunkwe vaċċin ieħor jew prodotti mediċinali oħra.
- Tiġborx vaċċin żejjed minn bosta kunjetti.

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.

Package leaflet: Information for the user

BIMERVAX® XBB.1.16 emulsion for injection
COVID-19 vaccine (recombinant, adjuvanted)
damlecovatein

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

Read all of this leaflet carefully before you recieve 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 BIMERVAX XBB.1.16 is and what it is used for

BIMERVAX XBB.1.16 is a vaccine used to prevent COVID-19 caused by the SARS-CoV-2 virus.

BIMERVAX XBB.1.16 is given to individuals 16 years of age and older.

The vaccine stimulates the immune system (the body's natural defences) to produce specific antibodies that work against the virus, giving protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

2. What you need to know before you receive BIMERVAX XBB.1.16

BIMERVAX XBB.1.16 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 receiving BIMERVAX XBB.1.16 if:
- you have ever had a severe or life-threatening allergic reaction after receiving any other vaccine injection;
- you have ever fainted following any needle injection;
- you have a high temperature (over 38 °C) or severe infection. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold;
- you have bleeding problems, you bruise easily or you use a medicine to prevent blood clots (anticoagulant medicine);

- your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants, or cancer medicines).

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist, or nurse before you are given BIMERVAX XBB.1.16.

As with any vaccine, BIMERVAX XBB.1.16 may not fully protect all those who receive it, and it is not known how long you will be protected.

Children and adolescents
BIMERVAX XBB.1.16 is not recommended for children aged below 16 years. Currently, there is no information available on the use of BIMERVAX XBB.1.16 in children younger than 16 years of age.

Other medicines and BIMERVAX XBB.1.16
Tell your doctor, pharmacist, or nurse if you are taking, have recently taken, or might take any other medicines or vaccines.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor, pharmacist, or nurse for advice before you receive this vaccine.

Driving and using machines
Some of the side effects of BIMERVAX XBB.1.16 listed in section 4 (Possible side effects) may temporarily reduce your ability to drive and use machines. Wait until any effects of the vaccine have worn off before you drive or use machines.

BIMERVAX XBB.1.16 contains sodium and potassium and polysorbate
This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

This vaccine contains less than 1 mmol potassium (39 mg) per 0.5 mL dose, that is to say, essentially 'potassium-free'.

This vaccine contains 1.18 mg of polysorbate 80 in each dose. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How BIMERVAX XBB.1.16 is given

Individuals 16 years of age and older
BIMERVAX XBB.1.16 will be given to you as 0.5 mL injection into a muscle of your upper arm.

It is recommended that you receive BIMERVAX XBB.1.16 as a single dose at least 6 months after a previous dose of a COVID-19 vaccine.

After the injection, your doctor, pharmacist or nurse will watch over you for around 15 minutes to monitor for signs of an allergic reaction.

If you have any further questions on the use of BIMERVAX XBB.1.16, ask your doctor, pharmacist or nurse.

Immunocompromised individuals
If your immune system does not work properly additional doses may be administered in line with official recommendations.

4. Possible side effects

Like all medicines, this vaccine can cause side effects, although not everybody gets them.

Most of the side effects occur within 3 days of getting the vaccine and go away within a few days of appearing. If symptoms persist, contact your doctor, pharmacist or nurse.

Get urgent medical attention if you get symptoms of a severe allergic reaction shortly after vaccination. Such symptoms may include:
- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat
- itchy swelling under the skin (hives) or rash
- feeling sick (nausea) or vomiting
- stomach pain

The following side effects may occur with BIMERVAX XBB.1.16:

Very common (may affect more than 1 in 10 people)
- headache
- pain where the injection is given
- feeling very tired (fatigue)
- muscle pain

Common (may affect up to 1 in 10 people)
- redness, swelling or tenderness where the injection is given
- feeling sick (nausea) or getting sick (vomiting)
- diarrhoea
- fever
- enlarged lymph nodes
- axillary pain

Uncommon (may affect up to 1 in 100 people)
- chills or feeling feverish
- dizziness
- itching where the injection is given
- joint pain
- feeling weak or lack of energy
- feeling sleepy
- itchy skin
- generally feeling unwell

Rare (may affect up to 1 in 1 000 people)
- cold sweating
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling of sensitivity, especially in the skin (hypoaesthesia)
- abdominal pain
- pain when swallowing
- allergic reactions such as hives, rash or itching
- bruise where the injection is given

- hypersensitivity where the injection is given

Not known (cannot be estimated from available data, based on a single case during clinical trials)
- inflammation of the lining outside the heart (pericarditis), which can result in breathless, palpitations or chest pain

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 vaccine.

5. How to store BIMERVAX XBB.1.16

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

Your doctor, pharmacist, or nurse is responsible for storing this vaccine and disposing of any unused product correctly. The following information about storage, expiry, use and handling as well as disposal is intended for healthcare professionals.

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

Store in a refrigerator (2 °C – 8 °C). Do not freeze. Keep the vials in the outer carton in order to protect from light.

Information on handling are described in the section intended for healthcare professionals at the end of the package leaflet.

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

6. Contents of the pack and other information

What BIMERVAX XBB.1.16 contains

- One dose (0.5 mL) contains 40 micrograms of damlecovatein adjuvanted with SQBA.

- Damlecovatein is SARS-CoV-2 virus recombinant spike (S) protein RBD fusion homodimer (Omicron XBB.1.16 – XBB.1.16 strain) produced by recombinant DNA technology.

- SQBA is included in this vaccine as an adjuvant to accelerate and improve the protective effects of the vaccine. SQBA contains per 0.5 mL dose: squalene (9.75 mg), polysorbate 80 (1.18 mg), sorbitan trioleate (1.18 mg), sodium citrate (0.66 mg), citric acid (0.04 mg) and water for injections.

- The other ingredients (excipients) are: disodium phosphate dodecahydrate, potassium dihydrogen phosphate, sodium chloride, potassium chloride and water for injections. BIMERVAX XBB.1.16 contains potassium, sodium and polysorbate (see section 2).

What BIMERVAX XBB.1.16 looks like and contents of the pack

The vaccine is a white homogeneous emulsion for injection.

0.5 mL of emulsion is provided in a vial with a rubber stopper and a plastic flip-off top.

Each single dose vial contains 1 dose of 0.5 mL

Pack sizes: 5, 10 or 20 single dose vials.

Marketing Authorisation Holder

Hipra Human Health, S.L.U.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

Manufacturer

Laboratorios Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: https://www.ema.europa.eu

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

Or visit the URL: www.hipracovidvaccine.com

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

The following information is intended for healthcare professionals only:

Administer BIMERVAX XBB.1.16 intramuscularly, preferably into the deltoid muscle of the upper arm.

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 and administration

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

This vaccine should be handled by a healthcare professional using aseptic techniques to ensure the sterility of each dose.

Preparation for use

- The vaccine comes ready to use.
- Unopened vaccine should be stored at 2 °C to 8 °C and kept within the outer carton to protect from light.
- Immediately prior to use, remove the vaccine vial from the outer carton.

Inspect the vial

- Gently swirl the vial before the dose withdrawal. Do not shake.
- Each vial contains a white and homogeneous emulsion.
- Visually inspect the vaccine for particulate matter and/or discolouration prior to administration. Do not administer the vaccine if any of these are present.

Administer the vaccine

- An overfill is included in each vial to ensure that one dose of 0.5 mL can be extracted. Discard any remaining vaccine in the vial.
- One 0.5 mL dose is withdrawn into a sterile needle and sterile syringe to be administered by intramuscular injection, preferably in the deltoid muscle of the upper arm.
- Do not mix the vaccine in the same syringe with any other vaccines or medicinal products.
- Do not pool excess vaccine from multiple vials.

Disposal

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